

PROVIDER REFERENCE MODULE

# Surgical Services

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POLICIES AND PROCEDURES AS OF AUGUST 1, 2019

VERSION: 4.0

Version	Date	Reason for Revisions	Completed By
1.0	Policies and procedures as of October 1, 2015	New document	FSSA and HPE
	Published: February 25, 2016		
1.1	Policies and procedures as of April 1, 2016 Published: July 12, 2016	Scheduled update	FSSA and HPE
1.2	Policies and procedures as of April 1, 2016	CoreMMIS update	FSSA and HPE
	(CoreMMIS updates as of February 13, 2017)		
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2.0	Policies and procedures as of May 1, 2017	Scheduled update	FSSA and DXC
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3.0	Policies and procedures as of May 1, 2018	Scheduled update	FSSA and DXC
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4.0	Policies and procedures as of August 1, 2019 Published: September 3, 2020	<ul> <li>Reorganized and edited text as needed for clarity</li> <li>Updated the initial note box with standard wording</li> <li>In the Multiple Procedures section, identified the applicable modifier, clarified its usage, and added a note regarding manually priced procedures</li> <li>Clarified information in the Bilateral Procedures section, including aligning descriptions for payment policy indicators with CMS terminology</li> <li>Added information regarding the payment policy indicator to the Cosurgeons section</li> <li>Added the Team Surgery section</li> <li>Updated the Assistant at Surgery section to clarify modifier usage and add information regarding the payment policy indicator</li> </ul>	FSSA and DXC

Version	Date	Reason for Revisions	Completed By
		Added clarifying text to the <u>Split Care</u> section and its subsections	
		• Added the <u>Return to Surgery</u> section	
		Updated the <u>Facility Billing</u> <u>and Reimbursement for</u> <u>Outpatient Surgeries</u> section,	
		including:  - Added a reference for inpatient facility billing	
		Noted an exception for manually priced procedures	
		Updated the list of treatment room revenue codes that can be used as surgical codes	
		Updated the <u>Multiple</u> <u>Surgeries and Bilateral</u> <u>Procedures</u> section and added a note about manually	
		<ul> <li>priced procedures</li> <li>Added the <u>Intrastromal</u> <u>Corneal Ring Segments</u> section</li> </ul>	
		Added a clarification in the VAD <u>Billing and</u> <u>Reimbursement</u> section that	
		the procedure is inpatient only and the VAD is not separately reimbursed	
		Added the <u>Lumbar</u> <u>Arthroplasty (Artificial Disc)</u> section	

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Note: The information in this module applies to Indiana Health Coverage Programs (IHCP) services provided under the fee-for-service (FFS) delivery system. For information about services provided through the managed care delivery system – including Healthy Indiana Plan (HIP), Hoosier Care Connect, or Hoosier Healthwise services – providers must contact the member's managed care entity (MCE) or refer to the MCE provider manual. MCE contact information is included in the IHCP Quick Reference Guide available at in.gov/medicaid/providers.

For updates to information in this module, see <u>IHCP Banner Pages and Bulletins</u> at in.gov/medicaid/providers.

#### Introduction

The Indiana Health Coverage Programs (IHCP) defines surgical services as services for a member requiring or seeking medically necessary perioperative care. Surgical services include, but are not limited to, preoperative preparation, operating room services, recovery room services, and outpatient admitting and discharge.

The IHCP provides coverage for inpatient and outpatient surgical services and associated implantable medical equipment within the guidelines described in this document.

For information about surgical procedures not mentioned in this module, see the module for the corresponding type of service; for example, see the <u>Obstetrical and Gynecological Services</u> module for information about hysterectomy and delivery procedures. For information on surgical supplies, see the <u>Durable and Home Medical Equipment and Supplies</u> module.

## **Prior Authorization for Surgical Services**

PA is required for all procedures outlined in Indiana Administrative Code 405 IAC 5-3-13.

Any surgical procedure usually performed on an outpatient basis, when scheduled as an inpatient procedure, must be prior authorized. The length of stay for the inpatient admission is determined by the appropriate diagnosis-related group (DRG), but is subject to retrospective review for medical necessity. Criteria for determining the medical necessity for inpatient admission include the following:

- Technical or medical difficulty during the outpatient procedure, as documented in the medical record
- Presence of physical or mental conditions that make prolonged preoperative or postoperative observations by a nurse or other skilled medical personnel a necessity
- Simultaneous performance of another procedure, which itself requires hospitalization
- Likelihood of another procedure that would require hospitalization following the initial procedure

Prior authorization (PA) for surgical services provided to IHCP fee-for-service (FFS) members must be requested from the FFS PA contractor. Members enrolled in a managed care program, such as HIP, Hoosier Care Connect, or Hoosier Healthwise, must be prior authorized by the MCE in accordance with the MCE guidelines.

See the *Prior Authorization* module for additional information regarding PA guidelines and procedures.

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## Professional Billing and Reimbursement for Surgical Services

Surgical procedures are based on the global concept that includes three parts:

- Preoperative management
- Intraoperative (surgical) care
- Postoperative management

## Preoperative Visits and Postoperative Care

Prior to the performance of a surgical procedure, either inpatient or outpatient, the member consults with the surgeon who will be performing the procedure. Reimbursement for a surgical procedure generally includes the preoperative visits performed on the same day as or the day before the surgery for major surgical procedures, and the day of the surgical procedure for minor surgical procedures. Separate reimbursement is available for preoperative care when the provider performing the surgery has never seen the patient, or when the decision to perform surgery was made during the preoperative visit. Modifier 57 – *Decision for surgery* must be submitted on the *CMS-1500* claim form or its electronic equivalent (837P transaction or Provider Healthcare Portal professional claim) with the evaluation and management (E/M) procedure code to indicate that the E/M service resulted in the initial decision to perform surgery. Preoperative visits performed on the same day as a surgical procedure may also be separately reimbursed if the patient is seen for evaluation of a separate clinical condition; see the *Evaluation and Management Services* module for details.

The postoperative care days for a surgical procedure include 90 days following a major surgical procedure and 10 days following a minor surgical procedure. Separate reimbursement is available during the global postoperative period for care that is unrelated to the surgical procedure, for care not considered routine, and for postoperative care for surgical complications.

The following perioperative encounters require additional, specific documentation:

- Surgery payable at reduced amount when related postoperative care paid
- Postoperative care within 0-90 days of surgery
- Preoperative care on day of surgery
- Surgery payable at reduced amount when preoperative care paid on the same date of service

## Medical Visits for Surgical Complications

Medical visits for surgical complication are reimbursed only if medically indicated and no other physician has billed for the same or related diagnosis. The claim must indicate the specific complications, and providers should attach documentation that clearly supports the medical necessity for the care provided. The medical visits are billed separately from the surgical fee. Such complications may include but are not limited to the following:

- Cardiovascular complications
- Comatose conditions
- Elevated temperature above 38.4° Celsius (101° Fahrenheit) for 2 or more consecutive days
- Medical complications, other than nausea and vomiting, due to anesthesia
- Nausea and vomiting persisting more than 24 hours
- Postoperative wound infection requiring specialized treatment
- Renal failure

## Multiple Procedures

When two or more covered surgical procedures are performed by the same physician during the same operative session, as identified modifier  $51 - Multiple\ procedures$  on the professional claim (CMS-1500 claim form or electronic equivalent), multiple-surgery reimbursement reductions are applied to the procedures, using the following adjustments:

- 100% of the global fee for the most expensive procedure
- 50% of the global fee for the second most expensive procedure
- 25% of the global fee for the remaining procedures

Note: Effective September 1, 2019, manually priced procedures are included in the multiplesurgery reimbursement reduction. For these procedures, the reduction will be applied to the lower of the billed amount or the IHCP-allowed amount for each unit billed.

All surgeries that are performed on the same day, by the same rendering physician, must be billed on the same professional claim form. Otherwise, the claim may be denied, and the original claim must be adjusted for any additional payment.

If the patient's condition requires additional medical or surgical care outside the scope of the operating surgeon – for example, a separate surgery performed by a different specialist for a different diagnosis – on the same day, reimbursement for the medical care is considered individually.

When a member requires two separate procedures performed during the same operative session by two surgical specialists, each surgeon may serve as the assistant surgeon during the other surgeon's procedure. Each surgeon may bill as primary surgeon for that portion of surgery for which he or she was responsible. See the <u>Assistant at Surgery</u> section for more information.

For information about the outpatient facility reimbursement methodology for multiple surgical procedures, see the *Facility Billing and Reimbursement for Outpatient Surgeries* section.

#### **Bilateral Procedures**

Bilateral surgery procedures are those performed on both sides of the body, during the same operative episode by the same provider. The IHCP applies Centers for Medicare & Medicaid Services (CMS) guidelines for professional reimbursement of bilateral procedures. Reimbursement is based on the Bilateral Surgery payment policy indicator assigned to the procedure code on the Medicare Physician Fee Schedule, as shown in Table 1.

If the applicable Current Procedural Terminology (CPT<sup>®1</sup>) code description does not specify that the procedure is bilateral, providers should include modifier 50 to indicate that the procedure was performed bilaterally. Only one unit should be billed for procedure codes with modifier 50. The use of modifier 50 ensures that the procedure code is priced according to the applicable indicator description in Table 1. If the CPT code description already specifies the procedure as bilateral, modifier 50 must *not* be used on the claim.

The explanations of benefits (EOBs) associated with modifier 50 in *Core*MMIS are as follows:

- EOB 4401 Modifier 50 "Bilateral" is invalid for the procedure billed. Please correct and resubmit.
- EOB 6426 Modifiers 50, RT, and LT, which were billed for this service, are not billable together. Please correct and resubmit.

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Table 1 – Medicare Physician Fee Schedule Payment Policy Indicators for Bilateral Surgery

Indicator	Description
0	150% payment adjustment for bilateral procedures does <b>not</b> apply.  Reimbursement for both sides is based on the lesser of the billed amount for both sides or the allowed amount for a single code.
1	150% payment adjustment for bilateral procedures applies.  Reimbursement for both sides is based on the lesser of the billed amount for both sides or 150% of the allowed amount for a single code.
2	150% payment adjustment does <b>not</b> apply.  The procedure is inherently bilateral and the reimbursement rate already includes payment for both sides. Reimbursement for both sides is based on the lesser of the billed amount for both sides or the allowed amount for a single code.
3	The usual payment adjustment for bilateral procedures does <b>not</b> apply.  Reimbursement for each side is based on the lesser of the billed amount for each side or the allowed amount <b>for each side</b> .
9	Concept does not apply. Services performed with modifier 50 will be systematically denied.

For information about the outpatient facility reimbursement methodology for bilateral procedures, see the *Facility Billing and Reimbursement for Outpatient Surgeries* section.

## Cosurgeons

When two surgeons are required to perform surgery on the same patient during the same operative session, both surgeons bill the procedure as a cosurgeon. Cosurgeons must append modifier 62 to the surgical service. Modifier 62 cuts the reimbursement rate to 62.5% of the rate on file.

Certain procedures do not allow for cosurgeon reimbursement. IHCP reimbursement for a procedure code billed with modifier 62 is based on the Cosurgeon payment policy indicator assigned to that code on the Medicare Physician Fee Schedule, as outlined in the following table. Claims submitted with inappropriate procedure code-modifier combinations will deny with EOB 4011 – *Invalid modifier combination*.

Table 2 – Medicare Physician Fee Schedule Payment Policy Indicators for Procedure Codes Billed with Cosurgeon Modifier 62

Indicator	Description
0	Modifier <b>not</b> allowed.
1	Modifier allowed.
2	Modifier allowed.
9	Modifier <b>not</b> allowed.

### Team Surgery

When more than two surgeons of differing specialties are required to perform surgery on the same patient during the same operative session, each surgeon bills the procedure as a team surgeon. Team surgeons must append modifier 66 to the surgical service. Modifier 66 does not affect the reimbursement rate, and each team surgeon is paid at 100% of the rate on file for applicable codes.

Certain procedures do not allow for team surgery reimbursement. IHCP reimbursement for a procedure code billed with modifier 66 is based on the Team Surgery payment policy indicator assigned to that code on the Medicare Physician Fee Schedule, as outlined in the following table. Claims submitted with inappropriate procedure code-modifier combinations will deny with EOB 4011 – *Invalid modifier combination*.

Table 3 – Medicare Physician Fee Schedule Payment Policy Indicators for Procedure Codes Billed with Team Surgeon Modifier 66

Indicator	Description
0	Modifier <b>not</b> allowed.
1	Modifier allowed.
2	Modifier allowed.
9	Modifier <b>not</b> allowed.

## Assistant at Surgery

A surgeon or other qualified practitioner may be requested to assist the performing surgeon during a complex surgical procedure. Documentation explaining the need for an assistant should be maintained, and one of the appropriate modifier must be used when submitting a claim:

- Physicians acting as assistants at surgery must bill using the appropriate modifier: modifiers 80 –
   *Assistant surgeon*, 81 *Minimum assistant surgeon*, or 82 *Assistant surgeon (when qualified resident surgeon not available)*. Reimbursement for procedures billed with these modifiers is cut back to 20% of the rate on file.
- Physician assistants or advanced practice registered nurses (APRNs) acting as assistant surgeons should use the AS modifier.

Certain procedures do not allow for reimbursement of an assistant during surgery. IHCP reimbursement for procedure codes billed with modifier 80, 81, 82, or AS is based on the Assistant at Surgery payment policy indicator assigned to that code on the Medicare Physician Fee Schedule, as outlined in the following table.

Table 4 – Medicare Physician Fee Schedule Payment Policy Indicators for Procedure Codes Billed with Surgical Assistant Modifiers 80, 81, 82, or AS

Indicator	Description
0	Modifier allowed.
1	Modifier <b>not</b> allowed.
2	Modifier allowed.
9	Modifier <b>not</b> allowed.

If extenuating circumstances require an assistant surgeon when customarily one is not required, the circumstances must be well documented in the hospital record. Reimbursement is not available for a surgical assistant who assists in diagnostic surgical procedures or for minor surgical procedures.

Claims submitted with inappropriate procedure code-modifier combinations will deny with EOB 4011 – *Invalid modifier combination*.

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### Split Care

Split care occurs when a component of the global surgery is rendered by a physician other than the physician performing the surgical service. Although there are three surgical procedure components, the IHCP recognizes split billing for only two of the components: intraoperative care and postoperative care. It is expected that the physician performing the intraoperative portion will perform the preoperative service. The IHCP does not recognize modifier 56 – *Preoperative care only* as a valid modifier. If a provider bills a service with modifier 56, the claim detail is denied with an invalid modifier message.

The IHCP requires a written agreement when a global surgical procedure is split among multiple providers. The conditions are the same as those for Medicare and are illustrated as follows:

- Providers billing for split care must have a written agreement outlining the date care is to be turned over and the name of the provider receiving the patient.
- The agreement must become part of the patient's file.
- The agreement must be submitted with any review or hearing request about the split-care payment.
- Modifiers 54 and 55 must be used if a written agreement exists.
- Physician must bill the appropriate CPT code without modifier 54 or 55 if a written agreement does not exist.

#### **Split-Care Billing Procedures and Reimbursement Calculation**

When the provider that performed the surgery does not provide any postoperative care, the provider must bill the surgical procedure code with modifier  $54 - Surgical \ care \ only$  and the actual date of the surgery.

The provider performing the postoperative care must bill the surgical procedure code with modifier 55 – *Postoperative management only*. The *dates of service* must reflect the date care was assumed and the date care was relinquished, and the *units* field must include the total number of postoperative days furnished. To ensure appropriate reimbursement when billing with modifier 55, the number of days within the *dates of service* range must equal the number of units (days) reported on the claim. For the purposes of defining postoperative care units, one unit is equal to one day of postoperative care.

Note: The postoperative period begins the day after surgery. Postoperative management claims must not be submitted until the physician managing the postoperative care sees the patient for the first time.

If the primary care physician is rendering the preoperative or postoperative care only, this information and the name and address of the **operating physician** must be indicated on the claim.

Providers that bill for only the intraoperative or postoperative component of surgery are reimbursed a percentage of the global fee shown on the IHCP Professional Fee Schedule. The percentage adjustment for modifiers 54 and 55 is specific to the surgical procedure.

The following two examples define appropriate billing procedures for split care and show how reimbursement is calculated. The examples use procedure code 43030, with a 90-day postoperative period and a total of \$379.82 allowed for the global service. Table 5 shows the adjustments applied for each component of the service.

Table 5 – Split-Care Reimbursement Adjustments for Procedure Code 43030

Description	Percentage	Modifier
Preoperative	9	
Intraoperative	+ 81	
Total intraoperative	90	54
Postoperative	10	55
Total	100	

#### Example 1

In this example, two physicians split the postoperative care. Physician A performs the surgical procedure and manages the patient postoperatively for 60 days, as shown in Table 6.

Table 6 - Billing Physician A

Physician A Claim	From Date of Service	To Date of Service	Procedure Code	Modifier	Units Billed
Detail 1	10/01/2019	10/01/2019	43030	54	1
Detail 2	10/02/2019	11/30/2019	43030	55	60

Reimbursement calculations for Physician A are made as follows:

**Detail 1:** Global fee of \$379.82 multiplied by 0.90 (9% for preoperative care + 81% for intraoperative care), multiplied by 1 unit billed equals **\$341.84**.

**Detail 2:** Global fee of \$379.82 multiplied by 0.10 equals the total postoperative allowance of \$37.982, which, divided by 90 (number of global days assigned), equals \$0.422 per day. That number multiplied by 60 (number of postoperative days reported) equals **\$25.32**.

As shown in Table 7, Physician B performs the balance of the postoperative care for 30 days.

Table 7 - Billing Physician B

Physician B Claim	From Date of Service	To Date of Service	Procedure Code	Modifier	Units Billed
Detail 1	12/01/2019	12/30/2019	43030	55	30

Reimbursement calculations for Physician B are made as follows:

**Detail 1:** Global fee of \$379.82 multiplied by 0.10 equals the total postoperative allowance of \$37.982, which, divided by 90 (number of global days assigned), equals \$0.422 per day. That number multiplied by 30 (number of postoperative days reported) equals **\$12.66**.

The combined total reimbursement for Physician A (\$367.16) and Physician B (\$12.66) equals the resource-based relative value scale (RBRVS) global fee amount of \$379.82.

Note: When only one provider is responsible for the surgery and all the postoperative care, the provider must bill the surgical procedure without modifier 54 or 55. The IHCP-allowed amount in this case would be 100% of the RBRVS fee. Modifiers 54 and 55 are used only to split postoperative care between multiple providers.

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#### Example 2

In this example, the same provider bills for the surgery and all the postoperative care. Physician A performs and bills for the surgical procedure and all the postoperative care, as shown in Table 8.

Table 8 - Billing Physician A

Physician A Claim	From Date of Service	To Date of Service	Procedure Code	Modifier	Units Billed
Detail 1	10/01/2019	10/01/2019	43030		1

Calculations are made as follows:

The global fee for procedure code 43030 is \$379.82. Therefore, reimbursement to Physician A for this service should be made at \$379.82.

#### **Exceptions and Special Billing Considerations for Split Care**

If more than one physician *in the same group practice* participates in a portion of a patient's care included in a global surgery package, only the physician who performs the surgery can submit a bill. Split-care modifiers are not applicable, and the surgeon's claim must include only the surgical procedure. Although other physicians participated in the care, all are within the same group practice. There is no need to split the reimbursement because the *physician group* is reimbursed the global fee.

If a transfer of care does not occur, occasional postdischarge services for a physician other than the surgeon are reported with the appropriate E/M code. Modifiers are not required.

If the transfer of care occurs immediately after surgery, the physician who provides the postoperative care while the patient remains in the hospital bills using subsequent hospital care codes. After the patient is released from the hospital, the physician responsible for postoperative care must bill using the surgical procedure code with modifier 55. The surgeon must bill the appropriate surgical procedure code with modifier 54.

If a physician provides follow-up services during the postoperative period for minor procedures performed in the emergency department, the physician must bill the appropriate level of office visit code. The emergency department physician who performed the surgical service must bill the surgical procedure code without a modifier.

If the services of a physician other than the surgeon are required during a postoperative period for an underlying condition or medical complication, the other physician must report the appropriate E/M code, and split-care modifiers are not required on the claim. For example, a cardiologist may manage the underlying cardiovascular condition during the postoperative period for a cardiovascular procedure that was performed by a cardiothoracic surgeon.

If a patient is returned to surgery for a related procedure during the postoperative period, the procedure must be billed using modifier 78. In this situation, the IHCP-allowed amount is calculated by multiplying the IHCP RBRVS fee amount by the intraoperative (surgical care only) percentage on the CMS Medicare Physician Fee Schedule. In these situations, the preoperative percentage is not added to the intraoperative percentage for calculating the allowed amount described in *Example 1*. In addition, a new postoperative period is not allowed for the related procedure. The number of postoperative days allowed following the return to surgery is equal to the number of postoperative days remaining from the original procedure.

Policies and procedures as of August 1, 2019 Version: 4.0 Billing certain modifiers on the same detail is restricted as follows to avoid processing issues:

- **Modifier 54** *Surgical care only* **cannot** be billed on the same detail as modifiers 55, 78, 80, 81, 82, AA, AS, P1–P5, QX, or QZ, or the detail denies for an invalid modifier combination.
- Modifier 55 Postoperative management only cannot be billed on the same detail as modifiers 54, 78, 80, 81, 82, AA, AS, P1–P5, QJ, QK, QX, or QZ, or the detail denies for an invalid modifier combination.

## Anesthesia and Surgery

The IHCP reimburses local anesthesia (therapeutic or regional blocks) as a surgical procedure. Time units or modifying factors associated with local anesthesia are not reimbursable. For additional information, see the *Anesthesia Services* module.

Reimbursement for anesthesia administered by the surgeon in conjunction with a surgical procedure is included in the fee for the surgical procedure.

## Return to Surgery

If a patient is returned to surgery for a related procedure during the postoperative period, and the service is billed using modifier 78 – *Return to the operating/procedure room for a related procedure during the postoperative period*, the percentage adjustment is specific to the surgical procedure.

For information about billing and reimbursement for return-to-surgery in a split-care situation, see the *Exceptions and Special Billing Considerations for Split Care* section.

## Facility Billing and Reimbursement for Outpatient Surgeries

Note: For information about facility billing for **inpatient** surgeries, see the <u>Inpatient Hospital</u> Services module.

The IHCP reimburses facility charges for outpatient surgeries at an all-inclusive rate that includes reimbursement for related procedures. Although a few outpatient surgery procedures are manually priced, most are classified into an IHCP ambulatory surgical center (ASC) group that is closest to, without exceeding, Medicare's outpatient prospective payment system fee schedule amount. All services are included in the all-inclusive reimbursement rate.

**Providers can obtain rate information and ASC assignment codes related to specific procedure codes on the Outpatient Fee Schedule**. The ASC Code/Rate table lists all ASC assignment codes, effective dates, and pricing. Both the Outpatient Fee Schedule and the ASC Code/Rate table are accessible from the <a href="https://linkowski.gov/medicaid/providers"><u>IHCP Fee Schedules page</u> at in.gov/medicaid/providers</a>.

Facilities must bill outpatient surgeries on an institutional claim (*UB-04* claim form, Provider Healthcare Portal institutional claim, or 837I electronic transaction). The appropriate surgical procedure code must accompany the applicable revenue code. The facility must include all outpatient services provided on the day of the surgery on a single claim. For more information about outpatient billing, see the *Outpatient Facility Services* module.

Surgical revenue codes are generally defined as 36X and 49X. Additionally, certain revenue codes for treatment rooms (450, 456, 459, 48X, 510, 511, 512, 514, 515, 516, 517, 519, 52X, 700, 710, 72X, 760, 761, 900, 907, 91X, and 972) are defined as surgical revenue codes when they are accompanied by a surgical procedure code. The IHCP reimburses these revenue codes at the appropriate ASC rate.

Library Reference Number: PROMOD00047 Published: September 3, 2020 Policies and procedures as of August 1, 2019 Providers combine all charges and services associated with the surgical procedure as an all-inclusive charge on one line item. Component billing of any related services is not appropriate and is denied.

Note: The IHCP does not allow add-on or stand-alone services with any surgical revenue codes.

## Multiple Surgeries and Bilateral Procedures

To denote multiple surgeries, the provider must list each appropriate revenue code and procedure code as separate detail line items on the institutional claim (*UB-04* claim form or electronic equivalent).

For outpatient billing, a maximum of two separate surgical procedures is reimbursable per member per day when performed in the same facility. The two procedures are reimbursed as follows:

- 100% of the global fee for the most expensive procedure
- 50% of the global fee for the second most expensive procedure

When multiple surgical procedures are performed within the same incision, the IHCP pays the procedure with the highest ASC rate at 100% of that rate. The procedure with the second highest ASC rate is reimbursed at 50% of its ASC rate. Additional procedures performed on the same day in the same facility are not reimbursed.

Note: Effective September 1, 2019, manually priced procedures are included in the multiplesurgery reimbursement reduction. For these procedures, the reduction will be applied to the lower of the billed amount or the IHCP-allowed amount for each unit billed.

The maximum IHCP reimbursement for each surgical procedure is two units of service to accommodate bilateral procedures. As described in the <u>Bilateral Procedures</u> section of this document, bilateral surgical procedures are generally reimbursed at 150% of the allowed amount:

- One unit is paid at 100% of the ASC rate.
- The second unit is reimbursed at 50% of the ASC rate.

Additional units are denied. Bilateral surgeries reimbursed at 150% of the ASC rate are considered two separate procedures; therefore, no additional procedures are reimbursed for that surgery.

Procedures billed with modifier 50 indicate a procedure that has been performed bilaterally. Bilateral procedures billed with modifier of 50 must not be billed with units greater than 1. Specific bilateral procedures (conditionally bilateral and independently bilateral) that are billed with a quantity greater than 1 are denied.

## **Provider Preventable Conditions**

The IHCP follows the Centers for Medicare & Medicaid Services (CMS) rule and does not cover surgical or other invasive procedures to treat particular medical conditions when the practitioner performs the surgery or invasive procedure erroneously, including:

- Incorrect surgical or other invasive procedures
- Surgical or other invasive procedures on the wrong body part
- Surgical or other invasive procedures on the wrong patient

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Policies and procedures as of August 1, 2019 Version: 4.0 The IHCP also does not cover hospitalizations or other services related to these noncovered procedures. All services provided in the operating room when an error occurs are considered related and therefore not covered. All providers in the operating room when the error occurs, that could bill individually for their services, are not eligible for payment. All related services provided during the same hospitalization in which the error occurred are not covered.

The IHCP will deny payments to providers for inpatient, outpatient, and professional claims (including Medicare and Medicare Replacement Plan crossover claims) when provider preventable conditions (PPC) are performed on a patient. For a list of PPC diagnosis codes, see *Surgical Services Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers. Providers may not bill the member for PPCs or related services upon denial of reimbursement by the IHCP.

The following PPC modifiers must be submitted on professional claims (including crossover claims) indicating errors:

- PA Surgery wrong body part
- PB Surgery wrong patient
- PC Wrong surgery on patient

## **Plastic or Reconstructive Surgery**

The IHCP covers reconstructive or plastic surgery for congenital defects, developmental anomalies, trauma, infection, tumors, or disease. The primary goal of reconstructive surgery is to improve function, but it may also be performed to reshape abnormal structures of the body and to allow a person to have a more normal appearance. PA is required for plastic or reconstructive surgery per 405 IAC 5-3-13.

## **Panniculectomy**

The IHCP covers panniculectomy when the service is provided in compliance with all IHCP guidelines. Panniculectomy is considered medically necessary when all the following criteria are met:

- Panniculus hangs at or below the level of the symphysis pubis, as demonstrated on preoperative photographs.
- Panniculus interferes with activities of daily living
- Panniculus causes a chronic and persistent skin condition (such as intertriginous dermatitis, panniculitis, cellulitis, or skin ulcerations) that is refractory to at least 6 months of medical treatment in addition to good hygiene practices. Treatment should include one or more of the following:
  - Topical antifungals
  - Topical and/or systemic corticosteroids
  - Local or systemic antibiotics

For any other indications, panniculectomy is not a covered service.

PA is required for a panniculectomy. Providers must submit a PA request with the appropriate clinical summary and physician's documentation supporting medical necessity. The following information must be included with the PA request:

- Member's diagnosis
- Member's current weight and height
- Preoperative photographs, front and lateral views
- History and physical (H&P) examination, including all previous surgeries and the member's weight loss history

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- Medical documentation of medical conditions and complications of infections outlining all treatments, including duration and responses
- Documentation of limitations on mobility and daily activities due to the panniculus or resulting complications

## Breast Plastic and Reconstructive Surgery

The IHCP covers breast plastic and reconstructive surgery, with PA, when related to disease or trauma deformity, per 405 IAC 5-29-1.

#### **Breast Reduction in Females**

The following PA criteria are required for IHCP reimbursement for breast reduction surgery in females. Documentation must be maintained in the member's medical record:

- History of the member's symptoms for at least 6 months related to the large, pendulous breasts must include the following:
  - Neck and shoulder pain
  - Low back pain
  - Strap-mark indentation
  - Restriction of physical activities
  - Poor posture
  - Skin irritation (submammary intertigo)
- Correcting the asymmetry of the breasts will not be authorized unless it is performed to achieve symmetry of the contralateral side when the opposite breast has been reconstructed after mastectomy for cancer.

#### **Breast Reduction in Males**

The IHCP covers breast reduction surgery in males older than 18 years of age (or 18 months after the end of puberty, for gynecomastia), when medically necessary. The following PA criteria are required:

- The tissue to be removed is glandular breast tissue and not the result of obesity, adolescence, or reversible effects of a drug treatment that can be discontinued. Documentation must be maintained in the medical record.
- Documentation in the medical record indicates conditions that may be associated with gynecomastia, including but not limited to the following:
  - Documented androgen deficiency
  - Chronic liver disease that causes decreased androgen availability
  - Klinefelter syndrome
  - Adrenal tumors that cause androgen deficiency or increased secretion of estrogen
  - Brain tumors that cause androgen deficiency
  - Testicular tumors causing androgen deficiency or tumor secretion of estrogen
  - Endocrine disorders, such as hyperthyroidism

#### **Noncovered Breast Reconstruction Services**

IHCP reimbursement is not available for breast reconstruction in the following cases:

- To reshape a normal structure to improve appearance or self-esteem
- For conditions not related to congenital defects, developmental anomalies, trauma, infection, tumors, or disease

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IHCP reimbursement is not available for procedures performed to address cosmetic symptoms, including ptosis, poorly fitting clothing, unacceptable appearance, or nipple-areolar distortion.

The use of liposuction to perform breast reduction is considered investigational and is noncovered.

## Genitourinary System Plastic and Reconstructive Surgery

Reconstructive surgery is considered medically necessary for missing, defective, damaged, or misshapen structures of the genitourinary system. Additionally, the IHCP provides reimbursement if a member has had significant alterations due to disease, trauma, surgery, or congenital anomalies.

#### Female Genitourinary Surgery

The IHCP reimburses for female genitourinary reconstructive surgery, with PA, for any of the following conditions:

- Agenesis of the vagina
- Post-trauma
- Post-cancer therapy

Documentation supporting medical necessity must be maintained in the medical record.

#### Male Genitourinary Surgery

The IHCP reimburses for male genitourinary reconstructive surgery, with PA, when both of the following conditions are met:

- Absence of testicle as a result of illness, injury, or congenital anomaly
- No evidence of active infection, malignancy, or current treatment for malignancy

Documentation supporting medical necessity must be maintained in the medical record.

#### Intersex Surgery

The IHCP defines intersex surgery as surgical intervention for members having congenital anomalies resulting in both male and female characteristics. The IHCP considers intersex surgery medically necessary for congenital anomalies resulting in a member having ambiguous genitalia. All other intersex surgery is not covered.

The IHCP provides reimbursement for intersex surgery, with PA, for congenital anomalies resulting in a member having ambiguous genitalia. Documentation supporting medical necessity must be maintained in the medical record.

#### Noncovered Genitourinary Services

Plastic or reconstructive surgery is noncovered unless related to disease or trauma deformity, per 405 IAC 5-29-1.

The IHCP does not provide reimbursement for the following:

- Penile implants
- Perineoplasty for sexual dysfunction
- Tubal reanastomosis for the purpose of infertility

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## Facial Plastic and Reconstructive Surgeries

The IHCP covers facial plastic or reconstructive surgery related to disease or trauma, specifically for surgery that alters the appearance of the lower face including the upper jaw, lower jaw, and chin. Surgery for these portions of the face may be indicated when severe abnormalities result in functional impairment affecting the ability to eat, swallow, or breathe. Procedures may be indicated to correct or restore appearance following traumatic injuries, or following medical or surgical treatments resulting in anatomical changes.

The IHCP covers facial plastic or reconstructive surgery, with PA, for members with mid-face disorders, nasal deformities, external ear disorders, and facial disorders. Providers are advised to report the most appropriate code for the procedure performed.

The following information must be maintained in the member's medical record:

- History of the presenting problem
- · Symptoms related to the facial disorder
- Previously attempted, less-invasive medical management treatment that has failed
- Any other medical documentation that supports the member's need of this service
- Absence of any additional medical condition jeopardizing the end result of the surgery, which could include, for example:
  - A suppressed immune system
  - A current infection unresponsive to medical management
  - Medical instability following illness or injury

#### Nasal Deformities – Rhinoplasty and Septoplasty

The IHCP covers rhinoplasty when considered medically necessary and when performed as a result of disease, structural abnormality, previous therapeutic process, or reconstruction due to trauma. Rhinoplasty is medically necessary when performed for correction or repair of the following conditions:

- Nasal deformity secondary to a cleft lip/palate or other congenital craniofacial deformity causing functional impairment
- Chronic, nonseptal, nasal obstruction due to vestibular stenosis (collapsed internal valves) secondary to trauma, disease, or congenital defect, when the member's condition is documented and both of the following criteria are met:
  - Nasal airway obstruction unresponsive to a recent trial of conservative medical management
  - Condition has not resolved or would not be expected to resolve with septoplasty/turbinectomy alone

The IHCP covers septoplasty for the following medically necessary conditions:

- · Recurrent epistaxis related to septal deformity
- Asymptomatic septal deformity that prevents access to other transnasal areas when such access is required to perform medically necessary procedures (such as ethmoidectomy)
- In association with cleft lip or cleft palate repair
- Obstructed nasal breathing due to septal deformity or deviation that is unresponsive to medical
  management and is interfering with the effective use of medically necessary CPAP for treatment of
  obstructive sleep disorder

PA is not required for members receiving rhinoplasty and septoplasty surgery related to a documented, primary diagnosis of cleft lip or cleft palate. See the <u>Cleft Lip and Cleft Palate</u> section for information regarding cleft lip and cleft palate services.

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All of the following documentation must be maintained in the member's medical record to confirm the medical necessity for rhinoplasty or septoplasty:

- Documentation of the extent of the deformity and associated symptoms
- Documentation of the plan for surgical correction
- Photographs to verify a plan that includes multiple surgeries
- Documentation of H&P examination, including any problems/congenital deformities that could
  potentially affect the outcome of the requested procedure
- Documented evidence of family/caregiver education about the plan of care and special health care needs of the member, before and after the surgery
- Statement that the requested surgery is expected to correct a specified portion of the deformity
- Statement that the requested surgery is expected to improve the member's functional status

#### **Eyelid Deformities - Blepharoplasty**

The IHCP covers blepharoplasties to improve abnormal function resulting in significant loss of visual field or to reconstruct deformity due to trauma or disease. The IHCP does not cover blepharoplasties to enhance the appearance of the eyes.

PA is required for all blepharoplasties, and documentation must support the medical necessity to improve abnormal function that has resulted in significant visual field loss or to reconstruct deformity due to trauma or disease. PA will be granted for blepharoplasty under the following indications:

- Upper eyelid blepharoplasty to relieve obstruction of central vision when all of the following criteria are met:
  - Visual field test without the eyelid or brow taped shows points of visual loss inside the 25° circle of the superior field
  - Visual field test with the eyelid or brow taped shows improvement in the superior field with no visual loss inside the 40° circle of the superior field
  - A photograph of the patient looking straight ahead shows the eyelid at or below the upper edge of the pupil
- Upper eyelid blepharoplasty for upper eyelid position that is contributing to prosthesis difficulties in an anophthalmic (complete absence of the eye) socket
- Lower eyelid blepharoplasty to relieve excessive lower lid bulk secondary to systemic corticosteroid therapy, myxedema, Graves' disease, nephritic syndrome, or other metabolic or inflammatory disorders that preclude proper positioning of eyeglasses
- Upper or lower eyelid blepharoplasty to treat chronic corneal exposure and/or recurrent corneal abrasions caused by conditions such as ectropion (eyelid turning outward) or entropion (eyelid turning inward)

## **Maxillofacial Surgery**

The IHCP provides coverage for maxillofacial surgery services. Based on the facts of the case, providers may be required to obtain a second or third opinion substantiating the medical necessity or approach for maxillofacial surgery related to diseases or conditions of the jaw and contiguous structures. This requirement applies regardless of the setting in which the procedure is to be performed.

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The IHCP covers the following maxillofacial services:

- Orthognathic (jaw realignment) surgery, with or without osteotomy
- Treatment of TMJ syndrome
- Removal of noncancerous cysts, tumors, and growths of the oral and facial region
- Surgical removal of impacted teeth
- Treatment of facial fractures
- Treatment of soft tissue trauma
- Osseointegrated (bone anchored) implants, including dental and craniofacial implants
- Adjunctive treatment of sleep apnea, including mandibular advancement splints and jaw advancement surgery
- Reconstructive surgery for disease or trauma
- Salivary gland surgery
- Radiology services for evaluation of maxillofacial anomalies
- Anesthesia services for maxillofacial surgery

## Orthognathic Surgery (Jaw Realignment)

The IHCP covers orthognathic surgery to correct jaw and craniofacial deformities causing significant functional impairment for members with congenital abnormality present at birth, or to treat a significant accidental injury, infection, or tumor when one or more of the following clinical indications are met:

- Anteroposterior discrepancies
  - Maxillary/mandibular incisor relationship: Overjet of 5 mm or more, or a value less than or equal to zero (norm 2 mm)
  - Maxillary/mandibular anteroposterior molar relationship: Discrepancy of 4 mm or more (norm 0 to 1 mm)

Note: These values represent two or more standard deviations (SDs) from published norms.

- Vertical discrepancies
  - Presence of a vertical facial skeletal deformity that is two or more SDs from published norms for accepted skeletal landmarks
  - Open bite
    - > No vertical overlap of anterior teeth
    - ➤ Unilateral or bilateral posterior open bite greater than 2 mm
  - Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch
  - Supraeruption of a dentoalveolar segment due to lack of occlusion
- Transverse discrepancies
  - A transverse skeletal discrepancy which is two or more SDs from published norms
  - Total bilateral maxillary palatal cusp to mandibular fossa discrepancy of 4 mm or greater, or a unilateral discrepancy of 3 mm or greater, given normal axial inclination of the posterior teeth
- Asymmetries
  - Presence of anteroposterior, transverse, or lateral asymmetries greater than 3 mm with concomitant occlusal asymmetry

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For IHCP coverage, one of the following symptoms must be present due to the malocclusion:

- Difficulty swallowing and/or choking, or ability to chew only soft or liquid food:
  - Symptoms must be documented in the medical record, must be significant, and must persist for at least 4 months.
  - Other causes of swallowing and/or choking problems must have been ruled out by history, physical exam, or appropriate diagnostic study, including but not limited to allergies, neurologic or metabolic diseases, and hypothyroidism.
- Speech abnormalities
  - Symptoms must have been determined by a speech pathologist or therapist to be due to the malocclusions and have not been improved by speech therapy or orthodontia.
- Malnutrition related to the inability to masticate:
  - Significant weight loss must be documented over 4 months, and a low serum albumin exists that is related to malnutrition.
- Intraoral trauma while chewing related to malocclusion or recurrent damage to the soft tissues of the mouth during mastication
- Significant obstructive sleep apnea (OSA) that is not responsive to or treatable by conservative means
  - Documentation must support that the OSA is significant and not responsive to or treatable by conservative means

An oral surgeon or a plastic surgeon may provide orthognathic surgical services as the maxillofacial specialist performing the procedure. Other specialists, such as an orthodontist or otolaryngologist, may be required to assist with the procedure. The procedure may be performed in an inpatient hospital, outpatient hospital, or ASC.

Anesthesia for orthognathic surgery may be performed by an anesthesiologist or certified nurse anesthetist, as medically appropriate.

## Temporomandibular Joint (TMJ) Syndrome

The IHCP covers both nonsurgical and surgical treatments for temporomandibular joint (TMJ) syndrome. IHCP members must receive a trial of conservative therapy before surgical treatment for TMJ syndrome will be prior authorized.

Documentation in the member's medical records must indicate that, before the patient was evaluated for surgical treatment of TMJ syndrome, at least **two** of the following forms of nonsurgical interventions were performed for a period of 3–6 months without adequate relief:

- Medical management Medical management may include nonopiate analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs) for mild-to-moderate inflammatory conditions and pain. Low-dosage tricyclic antidepressants may be prescribed for chronic pain, sleep disturbances, and nocturnal bruxism. Adjuvant pharmacologic therapies may include anticonvulsants, membrane stabilizers, and sympatholytic agents for unremitting pain, and opiate analgesics, corticosteroids, anxiolytics, and muscle relaxants for refractory pain. Osteopathic manipulative therapy may be included as part of the medical management. Medical management may be prescribed by a dentist, an orthodontist, an ear, nose, and throat (ENT) specialist, a psychiatrist, or an oral surgeon.
- **Physical therapy** Physical therapy may include active and passive jaw exercises, thermal modalities, manipulation modalities, electrogalvanic stimulation, and transcutaneous electrical nerve stimulation (TENS). Cranial manipulation, continuous passive motion, diathermy, infrared and ultrasound treatment, hydrotherapy, myofunctional therapy, iontophoresis, and neuromuscular reeducation are not considered medically necessary physical therapy treatments for TMJ syndrome.

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- Psychiatric/psychological therapy Psychiatric/psychological therapy may be initiated when TMJ syndrome is caused by a psychosomatic condition due to stress or anxiety. For example, bruxism, or teeth grinding, considered a psychophysiological disorder, is a common tension habit that can lead to TMJ syndrome. IHCP members without other obvious causative factors for TMJ symptoms (such as major trauma, arthritis, or jaw misalignment) should be evaluated for psychosomatic causes and treated appropriately. The IHCP provides reimbursement for psychiatric CPT codes in relation to treatment of TMJ syndrome when services are provided by any of the following:
  - Licensed physician
  - Licensed psychiatrist
  - Psychologist endorsed as a health service provider in psychology (HSPP)
- Mechanical therapy Mechanical therapy is provided through removable intra-oral appliances.
   Intra-oral appliances are used to treat members with dysfunctional occlusions. Treatment generally lasts for up to 6 months. Intra-oral appliances may be provided by a dentist, ENT specialist, orthodontist, or oral surgeon.

For coverage of surgical treatment of TMJ syndrome, the IHCP also requires (in addition to the aforementioned documentation of nonsurgical interventions) that one of the following indicate an intra-articular cause of TMJ syndrome:

- Physical exam
- Diagnostic x-rays
- Arthrography
- Orthopantogram and diagnostic imaging (computed tomography [CT], magnetic resonance imaging [MRI], or arthroscopy)

PA is required for the diagnosis of the TMJ, as well as for subsequent surgical treatment of TMJ syndrome when a member meets all the criteria listed for the type of treatment:

- Arthrocentesis is covered when the following conditions are met:
  - Persistent pain for more than 3–6 months that cannot be controlled by nonsurgical treatment
  - Clinical examination and/or diagnostic imaging that indicates the presence of hypomobility of the TMJ
  - Medically necessary instillation of therapeutic drugs into the joint
- Arthroscopy is covered when the following conditions are met:
  - Persistent pain for more than 3–6 months that cannot be controlled by nonsurgical treatment
  - Clinical examination and/or diagnostic imaging indicates joint pathology, such as internal derangement, hypomobility, or hypermobility that requires internal structural modification
- Arthrotomy, disc plication, discectomy, and arthroplasty with or without autograft and allograft are covered when the following conditions are met:
  - Persistent pain for more than 3–6 months that cannot be controlled by nonsurgical treatment
  - Severe, unremitting pain
  - Clinical examination and/or diagnostic imaging indicates joint pathology, such as internal
    derangement, hypomobility, or hypermobility that requires internal structural modification where
    minimally invasive surgery, such as arthrocentesis or arthroscopy, is not appropriate or has failed
- Arthroplasty with total prosthetic joint replacement is covered when the following conditions are met:
  - Inflammatory arthritis involving the TMJ which is not responsive to other modalities of treatment
  - Recurrent fibrosis and/or bony ankylosis that is not responsive to other modes of treatment
  - Failed tissue graft
  - Failed previous joint reconstruction
  - Loss of vertical mandibular condylar height due to bone reabsorption, trauma, developmental abnormality, or pathologic lesion

Documentation that the member meets the aforementioned criteria for the procedure must be submitted with the PA request and maintained in the member's medical record.

Local anesthesia is usually adequate for arthrocentesis and arthroscopic TMJ procedures. The local anesthesia is included in the reimbursement for the procedure. General anesthesia may be necessary for other TMJ procedures. General anesthesia may be performed by an anesthesiologist or certified nurse anesthetist, as medically appropriate.

## **Cleft Lip and Cleft Palate**

The IHCP requires the treatment of cleft lip and cleft palate be provided by a craniofacial interdisciplinary team of healthcare professionals. According to the American Cleft Palate-Craniofacial Association, the following health disciplines may be included in the overall treatment process:

- Anesthesiology
- Audiology
- Dentistry
- Genetic counseling
- Neurology
- Ophthalmology
- Oral and maxillofacial surgery
- Orthodontics
- Otolaryngology
- Plastic surgery
- Prosthodontics
- Radiology
- Speech-language pathology
- Social services

PA is not required for cleft lip and cleft palate services, except orthodontic services related to cleft palate.

## **Sinus Surgery**

The IHCP covers sinus surgery when the service is medically necessary for the member. Documentation of medical necessity must be maintained in the member's medical records.

## Functional Endoscopic Sinus Surgery

Functional endoscopic sinus surgery (FESS) is considered medically necessary for the treatment of sinusitis, polyposis, or sinus tumor under any of the following conditions:

- Suspected tumor seen on imaging, physical examination, or endoscopy
- Suppurative (pus forming) complications, including but not limited to:
  - Subperiosteal abscess
  - Brain abscess
- Chronic polyposis with symptoms unresponsive to medical therapy

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- Allergic fungal sinusitis, with all of the following:
  - Nasal polyposis
  - Positive CT findings
  - Eosinophilic mucus
- Mucocele causing chronic sinusitis
- Recurrent sinusitis with significant associated comorbid conditions
- Uncomplicated sinusitis (such as confined to paranasal sinuses without adjacent involvement of neurologic, soft tissue or bony structures) and all of the following:
  - Acute rhinosinusitis or chronic sinusitis, meeting either of the following criteria:
    - Four or more documented episodes of acute rhinosinusitis in one year
    - > Chronic sinusitis that interferes with lifestyle
  - Maximal medical therapy has been attempted, with all of the following:
    - Antibiotic therapy for at least 4 consecutive weeks
    - > Trial of inhaled steroids
    - ➤ Nasal lavage
    - Allergy testing (if symptoms are consistent with allergic rhinitis and have not responded to appropriate environmental controls and pharmacotherapy)
  - Abnormal findings from diagnostic workup, with any one of the following:
    - > CT findings suggestive of obstruction or infection
    - ➤ Nasal endoscopy findings suggestive of significant disease
    - ➤ Physical exam findings suggestive of chronic/recurrent disease
- Fungal mycetoma
- Previously failed sinus surgery
- Cerebrospinal fluid rhinorrhea
- Nasal encephalocele
- Posterior epistaxis (relative indication)
- Persistent facial pain after other causes ruled out (relative indication)
- Cavernous sinus thrombosis caused by chronic sinusitis

#### Balloon Sinus Ostial Dilation

Balloon sinus ostial dilation is medically necessary for treating chronic rhinosinusitis when all of the following criteria are met:

- Rhinosinusitis has lasted longer than 12 weeks.
- Chronic rhinosinusitis of the sinus to be dilated is confirmed on CT scan; CT scan findings of chronic rhinosinusitis include one or more of the following:
  - Mucosal thickening
  - Bony remodeling
  - Bony thickening
  - Obstruction of the ostiomeatal complex
- The member is older than 12 years of age.
- The member's symptoms persist despite medical therapy with one or more of the following:
  - Nasal lavage
  - Antibiotic therapy, if bacterial infection is suspected
  - Intranasal corticosteroids

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- Balloon sinus ostial dilation is limited to the frontal, maxillary, or sphenoid sinuses.
- Balloon sinus ostial dilation is performed either as a stand-alone procedure or as part of FESS.

## **Urethral Bulking Agents for Stress Urinary Incontinence**

Coverage of a urethral bulking agent and the procedure to inject it is limited to the following types of patients with stress urinary incontinence (SUI) because of intrinsic sphincter deficiency (ISD):

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias
- Male or female patients with acquired sphincter weakness secondary to spinal-cord lesions
- Male patients following trauma, including prostatectomy and/or radiation
- Female patients without urethral hypermobility and with abdominal leak point pressures (ALPPs) of 100 cm H<sub>2</sub>O or less

Patients whose incontinence does not improve with five injection procedures (five separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by urethral bulking agents is covered.

Patients who have a reoccurrence of incontinence following successful treatment with urethral bulking agents in the past (for example, 6 to 12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification.

## **Bariatric Surgery and Revisions**

Bariatric surgery is recognized as medically necessary when used for the treatment of morbid obesity. Providers must report ICD-10 diagnosis code E66.01 – *Morbid obesity* with the most specific procedure code available that represents the procedure performed.

All types of bariatric surgery require PA and are subject to the following conditions:

- The member is morbidly obese as defined by either of the following:
  - Body mass index (BMI)<sup>2</sup> of at least 35 with comorbidity or coexisting medical conditions, such as hypertension, cardiopulmonary conditions, sleep apnea, or diabetes
  - BMI of at least 40 without comorbidity
- Failed weight-loss therapy; the scope and duration of failed weight-loss therapy must meet the following criteria:
  - Unsuccessful weight-loss therapy:
    - Morbid obesity has persisted for at least 5 years and
    - Physician-supervised nonsurgical weight-loss program has been unsuccessful for at least 6 consecutive months

or

- Unsuccessful weight-loss maintenance:
  - ➤ Member successfully achieved weight loss after participating in a physician-supervised nonsurgical weight-loss program, but has been unsuccessful at maintaining weight loss for 2 years (> 3-kilogram [6.6-pound] weight gain).

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<sup>&</sup>lt;sup>2</sup> Body mass index is equal to weight in kilograms divided by height in meters squared.

Note: Successful weight-loss therapy is defined as the ability to reduce body weight by approximately 10% from baseline in a period of 8 months.

Unsuccessful weight-loss maintenance is defined as a weight regain of more than 3 kilograms (6.6 pounds) in 2 years and the inability to maintain a sustained reduction in waist circumference of at least 4 centimeters.

Members younger than 21 years of age must have documentation in the medical record by two
physicians who have determined bariatric surgery is necessary to save the life of the member or
restore the member's ability to maintain a major life activity.

In addition to the general coverage criteria for bariatric surgery, members under 18 years of age must also meet the following criteria:

- The member has reached sexual maturity and has reached a Tanner Scale stage IV or V plus 95% of predicted adult stature based on bone age.
- The member meets one of the following BMI/comorbidity requirements:
  - BMI greater than 35 with at least one of the following severe comorbidities that has significant short-term effects on health and that is uncontrolled with lifestyle or pharmacotherapy management:
    - > Type II diabetes mellitus
    - ➤ Moderate to severe sleep apnea (apnea-hypopnea index [AHI] ≥15)
    - > Severe nonalcoholic steatohepatitis
    - > Pseudotumor cerebri
  - BMI greater than or equal to 40 with at least one of the following comorbidities that is uncontrolled with lifestyle or pharmacotherapy management:
    - > Hypertension
    - > Insulin resistance
    - Glucose intolerance
    - > Substantially impaired quality of life or activities of daily living
    - > Dyslipidemia
    - $\triangleright$  Sleep apnea with AHI ≥ 5

## Prior Authorization for Bariatric Surgery

Prior authorization is required for all bariatric surgeries, as described in 405 IAC 5-3-13. The request for PA for bariatric surgery must be accompanied by the following documentation:

- A signed statement from the member acknowledging an understanding of pre- and postoperative expectations
- Documentation by the primary care physician of the results of the physician-supervised nonsurgical weight-loss program for at least 6 consecutive months, including unsuccessful weight loss or unsuccessful weight maintenance after successful weight loss
- Documentation by a psychiatrist or licensed HSPP that reflects a psychiatric evaluation for possible behavioral health conditions that are contraindications to the surgery
- Consultation reports from other practitioners (anesthesiologist, pulmonologist, cardiologist, and so on) who have seen the member for evaluation, if applicable.
- For members younger than 21 years of age, documentation by two physicians who have determined bariatric surgery is necessary to save the life of the member or restore the member's ability to maintain a major life activity

The physician requesting PA is responsible for referral of the member to a psychiatrist or a licensed HSPP at any time before or during the nonsurgical treatment. The consultation would include an assessment for any psychosocial needs with recommendation for treatment, if necessary. Documentation must be maintained in the member's medical record.

#### Noncovered Services for Bariatric Surgeries

The IHCP does not cover procedures that are considered investigational or not meeting safety or efficacy standards. The following bariatric procedures are not covered by the IHCP (this list may not be all-inclusive):

- Fobi-Pouch (limiting proximal gastric pouch)
- Gastroplasty (stomach stapling)
- Intestinal bypass (jejunoileal bypass)
- Intragastric balloon
- Loop gastric bypass
- Mini-gastric bypass
- Natural orifice transluminal endoscopic surgery (NOTES), such as StomphyX
- Panniculectomy following gastric bypass procedures performed for cosmetic reasons, even if performed incidentally to a ventral herniorrhaphy
- Laparoscopic adjustable gastric banding (LAGB) for children under the age of 18

## Surgical Revisions for Bariatric Surgery

Members may require subsequent surgery because of a complication during the perioperative period. They may also require a revision to correct a technical failure.

Prior authorization is required for reoperation to repair a complication or to correct a technical failure. PA for revision or conversion to Roux-en-Y includes a medical review of documentation. Documentation of medical necessity must include the reason for the failure and the date of the original surgery.

PA for revision of bariatric surgery due to the noncompliant behavior of the member requires 6 months of documentation in the medical record, to include the following:

- Member participation in all preoperative and postoperative evaluations and sessions included in the treatment plan
- Member participation in the preoperative and postoperative sessions with a bariatric dietician included in the treatment plan
- An evaluation by a psychiatrist or licensed HSPP that reflects the absence of behavioral health contraindications to a successful outcome to revision of the bariatric surgery

Note: PA is not required for HCPCS procedure code S2083 – Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline. This procedure is considered a routine, frequently performed, office procedure; it is not a surgical procedure. However, the IHCP does not provide reimbursement for HCPCS code S2083 during the 90-day global period for procedure codes 43770, 43771, 43773, 43886, and 43888, because adjustment is already included in the 90-day global period reimbursement for these services.

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## **Stereotactic Radiosurgery**

The IHCP currently covers several types of stereotactic radiosurgery (SRS), as represented by HCPCS codes G0339, G0340, and 77301 U5. In addition, the IHCP covers preoperative planning under HCPCS code 77301 U5. Reimbursement for physician services is bundled into the preoperative planning service.

## **Transplant Procedures**

The IHCP covers transplant procedures. PA is required for transplant surgeries per 405 IAC 5-3-13.

For all transplant procedures, documentation in the member's medical record must indicate that the following information was obtained within a medically reasonable time frame prior to the request for PA:

- H&P examination signed by a physician that includes the member's height, weight, and gender.
   Additionally, for members with a history of depression, suicide attempts, or drug dependence, the
   H&P examination documentation should include psychiatric or psychological evaluation signed by a
   psychiatrist or HSPP.
- Clear documentation of the disease status of the member, including copies of all recent results of imaging studies, bone marrow testing (when indicated), cytogenetics, and molecular studies.
- All current medication and treatment plans.

Refer to the following sections for additional documentation and PA requirements related to specific transplant procedures.

## Donor Hospital and Surgical Expenses

The IHCP covers the transplant donor's hospital and surgical expenses for the removal of the donor tissue or organ during the inpatient admission when all the following criteria are met:

- The recipient of the transplant is an IHCP member.
- The recipient meets criteria for the transplant.
- The transplant is considered medically necessary.

## Removal of Transplanted Organ

Certain organs may require removal following transplantation due to organ rejection.

Removal of a transplanted organ does not require PA. Transplantation of another organ does require a new PA request.

## Out-of-State Transplants

The IHCP covers transplant surgeries in out-of-state facilities when the hospital specializes in the particular transplantation procedure, or if the hospital is one of a limited number of hospitals that can perform the procedure.

All out-of-state services require prior authorization. The requests for these procedures are reviewed on an individual basis. For more information on out-of-state services, please see the *Out-of-State Providers* module.

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Policies and procedures as of August 1, 2019 Version: 4.0 Out-of-state providers who receive IHCP approval for transplantation will receive a written notification regarding how the claim will be reimbursed (either at the IHCP statewide rate or a percentage of the provider's usual and customary charge) and the coverage period (such as 365 days from transplant). The provider will be assigned a point of contact to assist with tracking expenditures and processing of payment for services. Outpatient lab services are paid at the IHCP rate on file, with no additional payment unless specific approval is given by the IHCP.

#### Corneal Tissue Transplant

The IHCP covers corneal transplantation with PA.

PA for corneal transplantation for **full thickness corneal disease** requires documentation of one of the following medical conditions:

- Bullous keratopathy
- Corneal opacity
- Corneal thinning with potential for corneal perforation
- Keratoconus with two or more episodes of corneal hydrops
- Keratoconus (conical protrusion of cornea caused by thinning of the stroma)
- Potential for corneal perforation

PA for corneal transplantation for **partial thickness corneal disease** requires documentation of one of the following medical conditions:

- Superficial stromal opacification
- Marginal corneal thinning or infiltration
- Localized corneal thinning or descemetocele formation

PA for transplantation of new tissue to the cornea for the treatment of **severe corneal surface disease reported with ocular surface reconstruction** requires documentation of one of the following medical conditions:

- Corneal pannus or superficial corneal scarring
- Persistent corneal epithelial defects
- Corneal perforation
- Neurotrophic keratitis
- Persistent corneal epithelial defects
- Bullous keratopathy
- Corneal thinning
- Corneal ulcer
- Chemical burns of the ocular surface
- Erythema multiforme, including Stevens-Johnson syndrome

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#### **Intrastromal Corneal Ring Segments**

Effective August 3, 2018, the IHCP covers CPT code 65785 – *Implantation of intrastromal corneal ring segments*. PA is required and the following criteria must be met:

- The member is 21 years of age or older.
- The procedure is for the treatment of keratoconus.
- The member has experienced a progressive deterioration in vision, such that he or she can no longer achieve adequate functional vision with contact lenses or spectacles.
- Corneal transplantation is the only alternative to improve the member's functional vision.
- The member has a clear central cornea with a corneal thickness of 450 microns or greater at the proposed incision site.

The following coverage limitations apply:

- Procedure code 65785 is considered **not medically necessary and therefore is not allowed** as a treatment of myopia.
- Procedure code 65785 is considered investigational and therefore is not allowed for all other conditions.

#### **Corneal Tissue Acquisition**

The cost associated with corneal tissue acquisition, HCPCS code V2785 – *Processing, preserving, and transporting corneal tissue*, is separately reimbursable from the ambulatory surgical center (ASC) rate for outpatient corneal transplant procedures. Claims for this item must be submitted on the professional claim (*CMS-1500* claim form or electronic equivalent). A copy of the invoice from the eye bank or organ procurement organization showing the actual cost of acquiring the tissue must be submitted as an attachment to the claim. HCPCS code V2785 is reimbursed 100% of the cost invoice.

## Bone Marrow or Stem Cell Transplant

The IHCP covers autologous or allogenic bone marrow or stem cell transplants with PA.

PA requires medical documentation of at least one of the following medical conditions:

- Adult or childhood acute myeloid leukemia (includes nonlymphocytic or nonlymphoblastic)
- Adult or high-risk childhood lymphocytic (lymphoblastic) leukemia in remission
- Myelodysplastic syndromes
- Acute lymphocytic or nonlymphocytic leukemia in remission
- Non-Hodgkin's lymphoma of intermediate and high grade (stage 3 or 4) in remission or with evidence of chemotherapy responsive disease
- Hodgkin's Disease (lymphoma) in second remission or refractory to primary therapy
- Congenital marrow failure syndromes unresponsive to medical therapy
- Severe aplastic anemia
- Severe combined immunodeficiency disease

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- Multiple myeloma
- Germ-cell cancer: recurrent or refractory to primary therapy
- Ovarian cancer
- Hurler's syndrome (other inherited metabolic diseases will be considered based on published literature)
- Ewing's sarcoma, limited to pulmonary relapse only
- Sickle cell anemia
- Thalassemia major or transfusion-dependent thalassemia intermedia

Note: Tandem stem cell transplants must receive PA as two separate procedures.

In addition, the member must meet **all** of the following criteria:

- The life expectancy following the transplant can reasonably be expected to be 1 year or more, measured by current standards.
- The member (or guardian) demonstrates a reasonable ability to comply with physician-directed postoperative treatments meant to reduce the chance of organ rejection.
- The adult member is competent and understands the risks and benefits of the transplant.
- The member has normal or treatable cardiovascular, pulmonary, hepatic, and renal function.

#### Noncovered Clinical Situations

The IHCP does not cover bone marrow or stem cell transplantations in the following clinical situations:

- The member is a juvenile and has no identifiable caretaker or no adequate family support structure.
- The member is septic or has an active infection.
- The member has a frank relapse or progression of leukemia or disease.
- The member has a condition preventing rehabilitation.
- The member's BMI is greater than 40.
- The member has an abnormal central nervous system (CNS) condition, such as cerebrovascular accident (CVA), organic brain syndrome, or dementia. (CNS metastasis as a consequence of the primary diagnosis for which the transplant is being requested would be excluded from this restriction.)
- The member has another active malignancy or history of active malignancy within 2 years, excluding skin cancers cured by simple excision. Documentation will be required at the time of PA request.
- The member has an AIDS diagnosis as defined by a CD4 count of less than 200 cells/mm³ unless all of the following are noted:
  - CD4 count greater than 200 cells/mm³
  - HIV-1 ribonucleic acid (RNA) undetectable
  - Stable anti-retroviral therapy for more than 90 days
  - No other complications from AIDS (such as opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, antimicrobial resistant fungal infections, or Kaposi's sarcoma or other neoplasms)
- The member is moribund.

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- The member has active alcohol or illegal-drug dependence within the 6 months prior to the submission of the request.
- The member has two or more significant abnormal lab or x-ray results, not related to the disease.
- The member has any of the following:
  - Congestive heart failure (systolic ejection fraction < 40%)</li>
  - Liver disease
  - Abnormal pulmonary function (diffusing capacity of the lungs for carbon monoxide [DLCO] < 60%)</li>
  - Renal failure (creatinine clearance < 40mg/dl)</li>

## Lung Transplant

The IHCP covers three components of lung transplantation with PA:

- Harvesting of the lung Includes cold preservation
- Backbench work Consists of preparation of cadaver donor lung or lungs prior to transplantation, including dissection of the lung from tissue around it and preparation of the pulmonary venous/atrial cuff, pulmonary artery, and bronchus bilaterally
- Recipient transplantation Includes transplanting a single lung or both lungs into the patient

PA requires medical documentation of at least one of the following medical conditions:

- Primary pulmonary hypertension
- Alpha-1 antitrypsin deficiency
- Interstitial lung disease
  - Pulmonary fibrosis (primary or secondary)
  - Usual interstitial pneumonitis
  - Fibrosing nonspecific interstitial pneumonitis
- Pulmonary fibrosis (primary or secondary)
- Cystic fibrosis
- Surfactant deficiency
- Bronchopulmonary dysplasia
- Pulmonary berylliosis (with chronic interstitial granulomatous fibrosis)
- Atrioventricular canal
- Chronic obstructive pulmonary disease (COPD) (chronic bronchitis, emphysema, bronchiolitis obliterans)
- Bronchiectasis
- Pulmonary vascular disease

#### **Noncovered Clinical Situations**

The IHCP does not cover lung transplantation in the following clinical situations:

- The member has active tobacco, alcohol, or illegal-drug dependence within the last 6 months.
- The member has active malignancy or other organ disease.

- The member has an AIDS diagnosis as defined by a CD4 count of less than 200 cells/mm³ unless all
  of the following are noted:
  - CD4 count greater than 200 cells/mm³
  - HIV-1 RNA undetectable
  - Stable anti-retroviral therapy for more than 90 days
  - No other complications from AIDS (such as opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, antimicrobial resistant fungal infections, or Kaposi's sarcoma or other neoplasms)

#### **Documentation**

The following documentation must be maintained in the member's medical record:

- No use of tobacco products for a period of 6 months prior to request or transplant
- Life expectancy without transplant is expected to be 18 months or less
- Life expectancy with transplant is expected to be 24 months or greater
- Ventilator dependency
- Urine drug screen within 90 days prior to submission of the request for members under 18 years of age or based on physician discretion
- Current prednisone use of less than 20 mg/day
- Karnofsky performance status > 70
- Chest x-ray, posteroanterior view
- CT scan of lungs (other CT scans as applicable)
- Thallium stress test results, or suitable alternative per a cardiologist, for members with history of significant cardiac risk factors
- Results of arterial blood gases (ABGs) and carboxyhemoglobin, and pulmonary function, including a
  forced expiratory volume (FEV) of 25% normal and decreasing forced vital capacity (FVC) of 40%
  normal or less
- Human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, and cytomegalovirus (CMV) serologies
- Lab values within normal limits
  - Complete blood count (CBC), urinalysis (UA), carcinoembryonic antigen (CEA), comprehensive metabolic panel (CMP)
  - Plasma ammonia
  - Creatine kinase (CK)
  - Serum magnesium
  - Lactic acid dehydrogenase
  - Serum phosphate
  - Platelet count
- Dental evaluation with treatment of any significant dental disease

## Heart Transplant

The IHCP covers three components of heart transplantation with PA:

- Cadaver donor cardiectomy Consists of harvesting and cold preservation of the graft prior to transport
- Backbench work Consists of dissection of the donor heart from surrounding soft tissue prior to transplantation and preparation of aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for transplantation
- Recipient transplantation Includes transplanting the heart into the patient

PA requires medical documentation of at least one of the following medical conditions:

- Eisenmenger's syndrome (ventricular septal defect [VSD] cardiac failure with significant right-to-left shunt producing cyanosis)
- Other complex congenital defects
- Myocardial failure unresponsive to medical management
- End-stage cardiomyopathy
- Inability to be weaned from temporary ventricular-assist devices after myocardial infarction (MI) or nontransplant cardiac surgery
- Valvular heart disease
- Intractable, life threatening arrhythmias unresponsive to medical treatment, surgery, ablation, or an implantable cardioverter-defibrillator

In addition, the member must also meet **all** of the following criteria:

- Life expectancy with current medical management is expected to be 12 months or less.
- Life expectancy after transplant is expected to be at least 2 years.
- The present degree of disability severely limits the member's activity (New York Heart Association [NYHA] class III or IV); see the <u>Classes of Heart Failure</u> page of the American Heart Association website at heart.org.
- The member (or guardian) demonstrates a reasonable ability to comply with postoperative treatments meant to reduce the possibility of organ rejection, including medication administration and cardiac biopsies.
- The adult member is competent and understands the risks and benefits of the transplant.
- The member is 1 week of age or older.

#### **Noncovered Clinical Situations**

The IHCP does not cover heart transplantations in the following clinical situations:

- The member is moribund.
- The member has fixed pulmonary hypertension or severe pulmonary disease (unless receiving combined heart/lung transplantation).
- The member has uncontrolled diabetes or uncontrolled hypertension.
- The member has hepatic fibrosis or cirrhosis.
- The member has hepatitis C with histological evidence of hepatic disease.

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- The member has uncorrected abdominal aneurysm greater than 4 centimeters.
- The member has a BMI > 40.
- The member has an abnormal central nervous system condition (such as cerebrovascular accident).
- The member has active malignancy or infection.
- The member has active systemic disease that would not be alleviated by the requested transplant or that severely limits life expectancy or precludes adequate post-transplant rehabilitation such as autoimmune or collagen vascular disease.
- The member has active gastrointestinal disease, such as bleeding peptic ulcer or diverticulitis.
- The member has active tobacco, alcohol, or illegal-drug dependence within the last 6 months.
- The member has an AIDS diagnosis as defined by a CD4 count of less than 200 cells/mm³ unless all of the following are noted:
  - CD4 count greater than 200 cells/mm³
  - HIV-1 RNA undetectable
  - Stable anti-retroviral therapy for more than 90 days
  - No other complications from AIDS (such as opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, antimicrobial resistant fungal infections, or Kaposi's sarcoma or other neoplasms)
- The member has uncontrolled or untreated psychiatric disorders that interfere with compliance to a strict treatment regimen.

#### **Documentation**

The following documentation must be maintained in the member's medical record:

- CBC, UA, and CMP
- Chest x-ray, posteroanterior view
- Urine drug screen within 90 days prior to submission of the request for members over 18 years of age or based on physician discretion
- Appropriate screening for colon cancer, if the member is over 40 years of age
- HIV, HBV, HCV, syphilis, and CMV serologies
- Results of electrocardiogram (EKG), multiple gate acquisition (MUGA) scan, heart catheterization(s), or electrophysiology (EP) studies
- Results of ABGs and pulmonary function tests if member was (or is) a smoker or has a history of lung disease (FEV less than 60% of normal and FVC less than 50% of normal may be a contraindication to transplant.)
- Dental evaluation with treatment of any significant dental disease

# Heart/Lung Transplant

The IHCP covers three components of heart/lung transplantation:

- Cadaver donor cardiectomy with pneumonectomy Consists of harvesting and cold preservation of the graft prior to transport
- Backbench work Includes dissection of the tissue around the heart and lungs and preparation of aorta, superior vena cava, inferior vena cava, and trachea for transplantation
- Recipient transplantation Includes transplanting the heart/lungs into the patient

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PA requires medical documentation that the criteria for both heart and lung transplantation are met.

#### Noncovered Clinical Situations

The IHCP does not cover heart/lung transplantation when any of the noncovered clinical situations for either a heart or lung transplantation are present.

#### **Documentation**

The IHCP requires documentation for heart/lung transplantation meet the same criteria required for both heart and lung transplantation.

# Liver Transplant

The IHCP covers three components of liver transplantation with PA:

- Cadaver or living donor hepatectomy Consists of harvesting and cold preservation of the graft prior
  to transplantation as well as care of the donor, in the case of living donor hepatectomy.
- Backbench work Consists of preparation of donor liver prior to transplantation, including the following:
  - Preparation of whole liver graft, including dissection and removal of surrounding tissue and soft tissue
  - Preparation of the vena cava, portal vein, hepatic artery, and common bile duct
  - Preparation of the whole liver with splitting of the liver for partial grafts (Additional reconstruction of the liver graft including venous and arterial anastomoses may also be performed.)
- Recipient transplantation Includes transplanting the liver into the patient and care of the recipient.

PA requires medical documentation of at least one of the following medical conditions:

- Acute liver failure due to viral hepatitis, drug reactions, or toxins
- Chronic liver failure due to any of the following:
  - Primary biliary cirrhosis
  - Chronic active hepatitis
  - Autoimmune hepatitis
  - Sclerosing cholangitis
  - Biliary atresia
  - Budd-Chiari syndrome
  - Alcoholic cirrhosis
  - Cryptogenic cirrhosis
  - Toxin induced cirrhosis
- Nonresectable, primary tumors of the liver, such as primary hepatomas and cholangiocarcinomas
- The development of life-threatening complications, including but not limited to the following:
  - Variceal hemorrhage
  - Encephalopathy
  - Spontaneous bacterial peritonitis
  - Hepatorenal syndrome
  - Intractable ascites
- Inborn errors of metabolism, such as the following:
  - Alpha-1 antitrypsin deficiency

- Wilson's disease
- Primary hyperoxaluria
- Primary hypercholesterolemia
- Tyrosinosis
- A traumatic or inflammatory noninfectious condition, other than metastatic cancer, which has
  resulted in the destruction of the liver or in the inability of the liver to function

In addition, the member must also meet all the following criteria:

- The member's life expectancy following transplant is expected to be at least 2 years
- The member (or guardian) demonstrates a reasonable ability to comply with post-operative treatments meant to reduce the possibility of organ rejection.
- The adult member is competent and understands the risks and benefits of the procedure.
- The juvenile member (or their guardians) understands the likelihood of growth retardation as a result
  of the liver condition.
- The member has normal or reversible cardiac, pulmonary, and renal function.

### **Noncovered Clinical Situations**

The IHCP does not cover liver transplantation in the following clinical situations:

- The member has sepsis.
- The member is greater than 70 years of age or less than 90 days of age.
- The member has any condition that would prevent rehabilitation.
- The member has any severe, uncorrectable pulmonary, cardiovascular, or renal dysfunction.
- The member has active extrahepatic infection (including metastatic hepatocellular carcinoma).
- The member has an abnormal central nervous system disorder (such as cerebrovascular accident).
- The member has an active extrahepatic malignancy.
- The member has an AIDS diagnosis as defined by a CD4 count of less than 200 cells/mm³ unless all of the following are noted:
  - CD4 count greater than 200 cells/mm³
  - HIV-1 RNA undetectable
  - Stable anti-retroviral therapy for more than 90 days
  - No other complications from AIDS (such as opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, antimicrobial resistant fungal infections, or Kaposi's sarcoma or other neoplasms)
- The member has active systemic disease, other than diabetes, that would not be alleviated by the requested transplant or would limit life expectancy or compromise recovery, such as systemic vasculitis.
- The member has active gastrointestinal disease, such as bleeding peptic ulcer or diverticulitis.
- The member is moribund.
- The member has active alcohol or illegal-drug dependence within the previous 6 months.
- The member has a Model for End-Stage Liver Disease (MELD) score < 15.
- The member has hepatocellular carcinoma with metastatic spread.
- The member has an anatomic abnormality that precludes liver transplantation.

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- The member has intrahepatic cholangiocarcinoma.
- The member has extrahepatic malignancy.
- The member has fulminant hepatic failure with sustained intracranial pressure (ICP) > 50 mm Hg or cerebral perfusion Pressure (CPP) < 40 mm Hg.
- The member has hemangiosarcoma.
- The member has demonstrated persistent noncompliance.
- The member lacks an adequate social support system.

#### **Documentation**

The following documentation must be maintained in the member's medical record:

- CBC, UA, and CMP
- EKG
- Chest x-ray, posteroanterior view
- Urine drug screen within 90 days prior to submission of the request for members over 18 years of age or based on physician discretion
- Appropriate screening for colon cancer if the member is over 50 years of age
- Thallium stress test results or suitable alternative per a cardiologist, if the member has a history of significant cardiac risk factors
- HIV, HBV, HCV, syphilis, and CMV serologies
- Results of ABGs and pulmonary function tests if member was (or is) a smoker or has a history of lung disease (FEV less than 60% of normal and FVC less than 50% of normal may be a contraindication to transplant.)
- Dental evaluation with treatment of any significant dental disease

# Kidney Transplant

The IHCP covers three components of kidney (renal) transplantation with PA:

- Cadaver or living donor nephrectomy Consists of harvesting and cold preservation of the graft prior to transplantation and care of the donor
- Backbench work Consists of preparation of the donor kidney prior to transplantation. This includes removal of perinephretic fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland; and preparation of ureters, renal veins, renal arteries, and ligating branches, as necessary. Other reconstruction procedures may involve venous, arterial, or ureteral anastomoses necessary for the transplant
- Recipient transplantation Includes transplanting the kidney into the patient

PA requires medical documentation of all of the following medical conditions:

- End-stage renal disease (ESRD)
- Glomerular filtration rate (eGFR) is < 30 mL/min/1.73 m<sup>2</sup>

#### **Noncovered Clinical Situations**

The IHCP does not cover kidney transplantation in the following clinical situations:

- The member has an active infection.
- The member has an active malignancy.
- The member has an active neoplastic disease.
- The member has active substance abuse.
- The member has an advanced cardiac disease.
- The member has an advanced pulmonary disease.
- The member has a chronic illness with shortened life expectancy.
- The member has reversible renal failure.
- The member has an uncontrolled psychiatric disease.
- The member has urologic or vascular problems.

#### **Documentation**

The following documentation must be maintained in the member's medical record:

- CBC, UA, and CMP
- EKG
- Chest x-ray, posteroanterior view
- CT scans or nuclear scan results when appropriate for the workup
- Urine drug screen within 90 days prior to submission of the request for members over 18 years of age or based on physician discretion
- Appropriate screening for colon cancer, for members over 50 years of age
- Thallium stress test results, or suitable alternative per a cardiologist, for members with history of significant cardiac risk factors
- HIV, HBV, HCV, syphilis, and CMV serologies
- Dental evaluation with treatment of any significant dental disease
- Results of ABGs and pulmonary function tests if member was (or is) a smoker or has a history of lung disease (FEV less than 60% of normal and FVC less than 50% of normal may be a contraindication to transplant.)

# Pancreatic Transplant

The IHCP covers three components of pancreatic transplants with PA:

- Cadaver pancreatectomy Consists of harvesting and cold preservation of the graft prior to transplantation.
- Backbench work Consists of preparation of the donor pancreas prior to transplantation. This
  includes preparation of the pancreas by dissecting the soft tissues surrounding the pancreas,
  splenectomy, duodenotomy, ligation of the bile duct, ligation of the mesenteric vessels, and Y-graft
  arterial anastomosis from the iliac artery to the superior mesenteric artery and to the splenic artery.
  Venous anastomosis(es) may also be included in reconstruction of the donor pancreas.
- Recipient transplantation Includes transplanting the pancreas into the patient.

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PA requires medical documentation of at least one of the following medical conditions:

- Type I diabetes mellitus
- Diabetic nephropathy with deteriorating or poor status
- Diabetic neuropathy
- Diabetic enteropathy
- Diabetic retinopathy, such as proliferative retinitis
- Diabetics who fail aggressive medical management of blood sugar
- Diabetics who demonstrate multiple episodes of ketoacidosis or hypoglycemia despite rigorous control and compliance
- Traumatic or inflammatory conditions, other than cancer, which has resulted in the destruction of the functional ability of the pancreas

In addition, the member must meet all of the following criteria:

- Life expectancy following the transplant can reasonably be expected to be 1 year, measured by current standards and the transplant results of the institution doing the procedure.
- The member (or guardian) demonstrates a reasonable ability to comply with the postoperative treatments meant to reduce the chance of organ rejection.
- The adult member is competent and understands the risks and benefits of the transplant.

#### **Noncovered Clinical Situations**

The IHCP does not cover pancreatic transplantation in the following clinical situations:

- The member has Type II diabetes.
- The member is moribund.
- The member has any condition preventing rehabilitation.
- The member has severe, uncorrectable pulmonary, cardiac, renal, or hepatic dysfunction.
- The member has an abnormal central nervous system condition (such as cerebrovascular accident).
- The member has an active malignancy, currently or within past 2 years.
- The member has an active infection.
- The member has an active systemic disease other than diabetes (such as systemic vasculitis).
- The member has an active gastrointestinal disease, such as bleeding peptic ulcer or diverticulitis.
- The member has active tobacco, alcohol, or illegal-drug dependence within the last 6 months.
- The member has an AIDS diagnosis as defined by a CD4 count of less than 200 cells/mm³ unless all of the following are noted:
  - CD4 count greater than 200 cells/mm³
  - HIV-1 RNA undetectable
  - Stable anti-retroviral therapy for more than 90 days
  - No other complications from AIDS (such as opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, antimicrobial resistant fungal infections, or Kaposi's sarcoma or other neoplasm)

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## **Documentation**

The following documentation must be maintained in the member's medical record:

- CBC, UA, and CMP
- EKG
- HIV, HBV, HCV, syphilis, and CMV serologies
- Chest x-ray, posteroanterior and lateral views
- CT scans or nuclear scan results when appropriate for the workup
- Urine drug screen within 90 days prior to submission of the request for members over 18 years of age or based on physician discretion
- Appropriate screening for colon cancer, results for members over 50 years of age
- Thallium stress test results, or suitable alternative per a cardiologist, for members with history of significant cardiac risk factors
- Results of ABGs and pulmonary function tests if member was (or is) a smoker or has a history of lung disease (FEV less than 60% of normal and FVC less than 50% of normal may be a contraindication to transplant.)
- Dental evaluation with treatment of existing caries

# Islet Cell Transplant

The IHCP covers islet cell transplantation with PA when medically necessary as an adjunct to a total or near total pancreatectomy in members with chronic pancreatitis.

#### **Noncovered Clinical Situations**

The IHCP does not cover pancreatic islet cell transplantation in the following clinical situations:

- Allogenic islet cell transplantation
- Treatment of type I diabetes
- Other applications for allogenic transplantation
- Active tobacco, alcohol, or illegal-drug dependence within the last 6 months

#### **Documentation**

The following documentation must be maintained in the member's medical record:

- HIV, HBV, HCV, syphilis, and CMV serologies
- Urine drug screen within 90 days prior to submission of the request for members over 18 years of age or based on physician discretion

# Intestinal (or Small Bowel) Transplant

The IHCP covers three components of intestinal (or small bowel) transplantation with PA:

• Cadaver or living donor enterectomy – Consists of harvesting and cold preservation of the graft prior to transplantation and care of the donor.

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- Backbench work Consists of preparation of donor intestine prior to transplantation, including:
  - Mobilizing and developing the superior mesenteric artery and vein
  - Any additional reconstruction of graft, including venous and arterial anastomoses, prior to transplantation
- Recipient transplantation Includes transplanting the intestine into the patient

The IHCP considers intestinal transplant medically necessary, with PA, for members with irreversible intestinal failure who can no longer be maintained on total parenteral nutrition (TPN). Clinical indications of TPN failure include the following:

- Impending or overt liver failure due to TPN; symptoms include:
  - Elevated bilirubin and/or liver enzymes
  - Gastroesophageal varices
  - Coagulopathy
  - Splenomegaly
  - Thrombocytopenia
  - Stomal bleeding
  - Hepatic fibrosis/cirrhosis
- Central line access failure as evidenced by:
  - Thrombosis of two or more of the major central channels (jugular, subclavian, and femoral veins)
  - Pulmonary embolism
  - Superior vena cava syndrome
  - Chronic venous insufficiency
- Two or more episodes of systemic sepsis due to line infection per year that requires hospitalization or a single episode of line-related fungemia, septic shock or acute respiratory distress syndrome
- Frequent episodes of severe dehydration despite IV fluid supplementation

PA for intestinal transplantation requires medical documentation of one of the following clinical indications for children or adults:

- Pediatric indications:
  - Aganglionosis (Hirschsprung's disease)
  - Congenital epithelial mucosal disease
  - (microvillus inclusion disease, tufting enteropathy)
  - Gastroschisis
  - Intestinal atresia
  - Necrotizing enterocolitis
  - Pseudo-obstruction
  - Radiation enteritis
  - Short gut syndrome
  - Volvulus
- Adult indications:
  - Crohn's disease
  - Desmoid tumors
  - Gardner's syndrome/familial polyposis
  - Hollow visceral myopathy
  - Inflammatory bowel disease
  - Ischemia
  - Short gut syndrome

- Surgical adhesions
- Trauma
- Volvulus

In addition, the member must also meet both of the following criteria:

- The member is capable of following a complex medical regimen post-transplantation.
- The member is emotionally stable with a realistic attitude demonstrated during past and current illness.

#### **Noncovered Clinical Situations**

The IHCP does not cover intestinal transplantation in the following clinical situations:

- The member has active malignancy, with the exception of squamous or basal cell carcinoma.
- The member has active or untreatable infections.
- The member has serious cardiac insufficiencies that create an inability to tolerate transplantation.
- The member has an active systemic illness.
- The member has active tobacco, alcohol, or illegal-drug dependence within the last 6 months.
- The member has demonstrated noncompliance with medical recommendations.
- The member has an AIDS diagnosis as defined by a CD4 count of less than 200 cells/mm³ unless all of the following are noted:
  - CD4 count greater than 200 cells/mm³
  - HIV-1 RNA undetectable
  - Stable anti-retroviral therapy for more than 90 days
  - No other complications from AIDS (such as opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, antimicrobial resistant fungal infections, or Kaposi's sarcoma or other neoplasm)

#### **Documentation**

The following documentation must be maintained in the member's medical record:

- Chemistries, including CBC, CMP, UA, and creatinine clearance (if creatinine is greater than 2.0)
- Lipid and hepatic function panels
- HIV, HBV, HCV, syphilis, and CMV serologies
- Urine drug screen within 90 days prior to submission of the request for members over 18 years of age or based on physician discretion
- Recent EKG and chest x-ray, posteroanterior view
- Psychosocial evaluation, performed at the transplant center
- Dental evaluation with treatment of any significant dental disease

# Multivisceral Transplant

The IHCP covers three components for each organ included in the multivisceral transplant with PA:

• Cadaver or living donor enterectomy – Consists of harvesting and cold preservation of the organs prior to transplantation, as well as care of the donor (in the case of living donor)

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- Backbench work Consists of preparation of donor organs prior to transplantation
- Recipient transplantation Includes transplanting the organs into the patient

PA requires medical documentation of at least one of the following medical conditions:

- Irreversible intestinal and multivisceral organ failure that can no longer be maintained with TPN
- Total occlusion of the splanchnic circulation
- Extensive GI polyposis
- Myopathy or neuropathy of the hollow viscera
- Abdominal malignancy

Note: Members must meet the PA criteria listed in this module for intestinal, liver, and/or pancreatic transplantation in order to qualify for multivisceral transplantation of these organs. Providers should refer to the <a href="Intestinal (or Small Bowel) Transplant">Intestinal (or Small Bowel) Transplant</a> section for indications of intestinal failure and TPN failure.

In addition, the member must also meet both of the following criteria:

- The member is capable of following a complex medical regimen post-transplantation.
- The member is emotionally stable with realistic attitude demonstrated during past and current illness.

## **Noncovered Clinical Situations**

The IHCP does not cover multivisceral transplantation in the following clinical situations:

- The member has an active malignancy, with the exception of squamous or basal cell carcinoma.
- The member has ongoing, recurring, or unsuccessfully treated infections.
- The member has serious cardiac insufficiencies that create an inability to tolerate transplantation.
- The member has active systemic illness.
- The member has active tobacco, alcohol, or illegal-drug dependence within the last 6 months.
- The member has demonstrated noncompliance with medical recommendations.
- The member has an AIDS diagnosis as defined by a CD4 count of less than 200 cells/mm³ unless all of the following are noted:
  - CD4 count greater than 200 cells/mm³
  - HIV-1 RNA undetectable
  - Stable anti-retroviral therapy for more than 90 days
  - No other complications from AIDS (such as opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, antimicrobial resistant fungal infections, or Kaposi's sarcoma or other neoplasm)

#### **Documentation**

The following medical documentation must be maintained in the member's medical record:

- Chemistries, including CBC, CMP, UA, and creatinine clearance (if creatinine is greater than 2.0)
- Lipid and hepatic function panel
- HIV, HBV, HCV, syphilis, and CMV serologies

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- Urine drug screen within 90 days prior to submission of the request for members over 18 years of age or based on physician discretion
- Recent EKG and chest x-ray, posteroanterior view
- Psychosocial evaluation, performed at the transplant center
- Dental evaluation with treatment of any significant dental disease

# Implantable DME

For certain implantable durable medical equipment (DME), the cost of the device is separately reimbursable, in addition to the outpatient facility claim for the implantation procedure. See the Separately Reimbursable DME When Implanted in an Outpatient Setting section. Providers should carefully review the following sections for information about whether an implantable device is separately reimbursable, as well as for PA requirements and billing guidance.

The IHCP provides reimbursement for removal of medical implants (such as pins, screws, rods, plates, and so on) when a fracture has healed or the symptoms that required implantation of the device abate. Implant removals requiring an operating room are usually considered minor procedures and the rules governing minor procedures in 405 IAC 5-28-1 apply. Some implants may be removed in the physician's office.

#### Artificial Heart

The IHCP covers artificial hearts for bridge-to-transplant for members who meet all of the following criteria:

- The member must be at risk of imminent death from nonreversible biventricular heart failure (NYHA class IV).
- The member does not respond to other treatments.
- The member has been prior authorized for a heart transplant (excluding dual eligible members).
- The member is listed as a candidate for heart transplantation by a Medicare-/Medicaid-approved heart transplant center.
- If the artificial heart is implanted at a different site than the Medicare-/Medicaid-approved transplant center, the implanting site must receive written permission from the Medicare-/Medicaid-approved center under which the patient is listed prior to implantation of the artificial heart.

PA is required for implantation of an artificial heart. To be eligible for implantation of an artificial heart, the member must meet all PA criteria for a heart transplant. Additionally, documentation must be provided showing that the member is currently listed as a heart transplantation candidate or is undergoing evaluation to determine candidacy for heart transplantation and is not expected to survive until a donor heart can be obtained.

#### **Noncovered Clinical Situations**

The IHCP does not cover artificial hearts in the following clinical situations:

- Use of an artificial heart that is not approved by the Food and Drug Administration (FDA) is considered investigational and is a noncovered service.
- Use of an FDA-approved artificial heart in a manner that is not approved by the FDA is considered investigational and is a noncovered service.
- The artificial heart is noncovered for destination therapy.
- The artificial heart is noncovered for treatment of postcardiotomy cardiogenic shock.

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## Cardiac Pacemakers

The IHCP covers implantation of cardiac pacemakers and monitoring. Prior authorization is not required for the implantation of a pacemaker when performed in an outpatient setting. Documentation must be maintained in the member's medical record to support medical necessity.

## Single-Chamber Cardiac Pacemaker

The IHCP covers the implantation of the single-chamber cardiac pacemaker for members who meet any of the following conditions, provided the condition is chronic or recurrent, and not due to transient causes (such as acute myocardial infarction, drug toxicity, or electrolyte imbalance):

- Acquired complete (also referred to as third degree) atrioventricular (AV) heart block
- Congenital complete heart block with severe bradycardia in relation to age or significant physiological deficits or significant symptoms due to the bradycardia
- · Second degree AV heart block of Type II
- Second degree AV heart block of Type I
- Sinus bradycardia associated with major symptoms or substantial sinus bradycardia with heart rate less than 50 associated with dizziness or confusion\*
- Sinus bradycardia of lesser severity (heart rate 50 to 59) with dizziness or confusion\*
- Sinus bradycardia that is the consequence of long-term, necessary drug treatment for which there is no acceptable alternative, when accompanied by significant symptoms\*
- Sinus node dysfunction, with or without tachyarrhythmia or AV conduction block, when accompanied by significant symptoms
- Sinus node dysfunction, with or without symptoms, when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia
- Bradycardia associated with supraventricular tachycardia with high degree AV block, which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms
- Hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures
- Bifascicular or trifascicular block accompanied by syncope, which is attributed to transient complete
  heart block after other plausible causes of syncope have been reasonably excluded
- Prophylactic pacemaker use following recovery from acute myocardial infarction during which there
  was temporary complete (third degree) or Mobitz Type II second-degree AV block in association
  with bundle branch block
- Recurrent and refractory ventricular tachycardia, overdrive pacing (pacing above the basal rate) to prevent ventricular tachycardia
- Second-degree AV heart block of Type I with the QRS complexes prolonged

\*Note: For conditions marked with an asterisk (\*), the correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

#### Noncovered Clinical Situations

The IHCP does not cover implantation of the single-chamber pacemaker for the following clinical conditions:

- Syncope of undetermined cause
- Sinus bradycardia without significant symptoms
- Sinoatrial block or sinus arrest without significant symptoms
- Prolonged PR intervals (slow ventricular response) with atrial fibrillation without third-degree AV block
- Bradycardia during sleep
- Right bundle branch block with left axis deviation and other forms of fascicular or bundle branch blocks without significant signs or symptoms
- Asymptomatic second-degree AV block of Mobitz Type I (Wenckebach)

## **Dual-Chamber Cardiac Pacemaker Implantation**

The IHCP covers implantation of the dual-chamber cardiac pacemaker for members who meet any of the following conditions, provided the condition is chronic or recurrent, and not due to transient causes (such as acute myocardial infarction, drug toxicity, or electrolyte imbalance):

- A definite drop in blood pressure, retrograde conduction, or discomfort during insertion of a singlechamber (ventricular) pacemaker
- Pacemaker syndrome (AV asynchrony) with significant symptoms with a pacemaker that is being replaced
- A condition in which even a relatively small increase in cardiac efficiency will importantly improve the quality of life
- A condition in which the pacemaker syndrome can be anticipated
- Any of the conditions listed under the single-chamber pacemaker implantation, if the dual-chamber pacemaker is determined to be medically necessary.
- Prophylactic pacemaker use following recovery from acute myocardial infarction during which there
  was temporary complete (third degree) or Mobitz Type II second-degree AV block in association
  with bundle branch block.

#### Noncovered Clinical Situations

The IHCP does not cover implantation of the dual-chamber pacemaker for the following clinical conditions:

- Ineffective atrial contractions
- Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of the tachycardia
- A clinical condition in which pacing takes place only intermittently and briefly and is not associated with a reasonable likelihood that pacing needs will become prolonged

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## **Billing and Reimbursement**

The IHCP reimburses the cost of the cardiac pacemakers separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table listed in *Surgical Services Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

The facility purchasing the pacemaker must submit a manufacturer's cost invoice, showing the purchase price for the pacemaker, as an attachment to the professional claim (*CMS-1500* claim form or electronic equivalent). The IHCP reimburses the provider at 120% of the cost invoice for this device.

## **Monitoring of Pacemakers**

The IHCP covers clinic and telephone monitoring of cardiac pacemakers when the frequency of monitoring does not exceed the values shown in Table 9, unless medically necessary.

Table 9 – Cardiac Pacemaker Monitoring Frequency

Type of Monitoring	Frequency
For clinic monitoring of lithium battery pacemakers with single-chamber pacemakers	Twice in the first 6 months following implant, then once every 12 months
For clinic monitoring of lithium battery pacemakers with dual-chamber pacemakers	Twice in the first 6 months following implant, then once every 6 months
For clinic monitoring of lithium battery pacemakers with single- or dual-chamber pacemakers within the final 12 months of anticipated pacemaker battery depletion	Up to once every 2 months for members with documented pacemaker dependence without access to telephone monitoring
For clinic monitoring of lithium battery pacemakers with single- or dual-chamber pacemakers demonstrating documented evidence of pacing system failure or malfunction	Increased follow-up frequency will be covered if determined to be medically necessary
For telephone monitoring with single-chamber pacemaker following the first month of the implant	Once every 2 weeks
For telephone monitoring with single-chamber pacemaker following the second month of the implant through the 36th month	Once every 8 weeks
For telephone monitoring with single-chamber pacemaker following the 37th month of the implant through failure	Once every 4 weeks
For telephone monitoring with dual-chamber pacemaker following the first month of the implant	Once every 2 weeks
For telephone monitoring with dual-chamber pacemaker following the second through the sixth month of the implant	Once every 4 weeks
For telephone monitoring with dual-chamber pacemaker following the seventh through the 36th month of the implant	Once every 8 weeks
For telephone monitoring with dual-chamber pacemaker following the seventh through the 37th month through failure of the implant	Once every 4 weeks

# Cochlear Implants

The IHCP covers cochlear implants when medically necessary and with PA for the cochlear implantation procedure and for all required prerequisite testing and documentation.

PA requires medical documentation of all of the following medical conditions:

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment (HI) with limited benefit from appropriate hearing (or vibrotactile) aids
- Cognitive ability to use auditory clues and willingness to undergo an extended program of rehabilitation
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system

For information about maintenance and repair of the cochlear implant, see the <u>Hearing Services</u> module.

## **Billing and Reimbursement**

For dates of service on or after October 4, 2018, the IHCP reimburses the cost of the cochlear device separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers.

# Implantable Cardioverter Defibrillators

The IHCP covers implantable cardioverter defibrillators, including subcutaneous implantable cardioverter defibrillators (S-ICDs), with PA, when the member is receiving optimal medical therapy and has a reasonable expectation of survival with good functional status for more than 1 year.

#### Indications - General

PA requires medical documentation of at least one of the following medical conditions:

• The member is a survivor of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained ventricular tachycardia (VT) after evaluation to define the cause of the event and to exclude any completely reversible causes.

All the following must also be met:

- Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography.
- Myocardial infarctions (MIs) must be documented and defined according the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction (see the <u>Journal of the American College of Cardiology article</u> at onlinejacc.org).
- The member has left ventricular (LV) dysfunction with prior myocardial infarction (ischemic cardiomyopathy) with one of the following:
  - Left ventricular ejection fraction (LVEF) less than or equal to 35% due to prior myocardial infarction, is at least 40 days post-myocardial infarction, and is in NYHA class II or III.
  - LV dysfunction due to prior myocardial infarction, is at least 40 days post-myocardial infarction,
     LVEF less than or equal to 30%, and is in NYHA class I
  - Nonsustained VT due to prior myocardial infarction, LVEF less than or equal to 40%, and inducible ventricular fibrillation or sustained VT at electrophysiological study

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All the following must also be met:

- Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography.
- MIs must be documented and defined according the Joint European Society of Cardiology/ American College of Cardiology Committee for the Redefinition of Myocardial Infarction.
- The member has nonischemic dilated cardiomyopathy with LVEF less than or equal to 35% and is in NYHA class II or III.
- The member has sustained VT, either spontaneous or induced by an EP study, not associated with an
  acute MI and not due to a transient or reversible cause
- The member has syncope of undetermined origin with one of the following:
  - Clinically relevant, hemodynamically significant sustained VT
  - Ventricular fibrillation induced at electrophysiological study
  - Unexplained syncope, significant LV dysfunction, and nonischemic dilated cardiomyopathy
- The member has a familial or inherited condition with a high risk of life-threatening VT (one of the following):
  - Hypertrophic cardiomyopathy with one or more of the following major risk factors for sudden cardiac death (SCD):
    - Prior cardiac arrest
    - > Spontaneous sustained VT
    - > Spontaneous nonsustained VT
    - > Family history of SCD
    - Syncope
    - > LV thickness greater than or equal to 30 mm
    - ➤ Abnormal blood pressure response to exercise
  - Arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) with one or more risk factors for SCD:
    - ➤ Induction of VT during electrophysiological testing
    - > Detection of nonsustained VT on noninvasive testing
    - Male gender
    - > Severe right ventricular dilation
    - > Extensive right ventricular involvement
    - > Young age at presentation (less than 5 years)
    - ➤ LV involvement
    - > Prior cardiac arrest
    - Unexplained syncope
    - Deleterious genetic mutations associated with ARVD/C
  - Long QT syndrome in a member who is experiencing syncope and/or VT while receiving beta blockers
- The member has catecholaminergic polymorphic VT and has syncope and/or documented sustained VT while receiving beta blockers.
- The member has cardiac sarcoidosis, giant cell myocarditis, or Chagas disease.
- The member has brugada syndrome and one of the following:
  - Previous syncope
  - Documented VT that has not resulted in cardiac arrest
- The member is nonhospitalized and is awaiting transplantation.

## Indications for Pediatric Members and Members with Congenital Heart Disease

The IHCP covers implantable cardioverter defibrillator for pediatric members and members with congenital heart disease who have one of the following conditions:

- The member is a survivor of cardiac arrest, after evaluation to define the cause of the event and to exclude any reversible causes.
- The member has symptomatic sustained VT in association with congenital heart disease, and has undergone hemodynamic and electrophysiological evaluation.
- The member has congenital heart disease with recurrent syncope of undetermined origin in presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study.
- The member has recurrent syncope associated with complex congenital heart disease and advanced systemic ventricular dysfunction, when thorough invasive and noninvasive investigations have failed to define a cause.

#### **Noncovered Clinical Situations**

The IHCP does not cover implantable cardioverter defibrillators in the following clinical situations:

- The member has irreversible brain damage, disease, or dysfunction that precludes the ability to give informed consent.
- The member has significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up.
- The member has any disease other than cardiac disease (such as cancer, uremia, liver failure, advanced cerebrovascular disease) associated with survival less than 1 year.
- The member has ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (such as electrolyte imbalance, drugs, or trauma).
- The member has an asymptomatic VT or symptomatic VT/VF that is:
  - Associated with acute MI within 2 days
  - Due to a remediable cause
  - Controlled by appropriate drug therapy
  - Manageable through the use of other therapies (such as ablation procedures, surgery)
- The member has incessant VT or ventricular fibrillation.
- The member has syncope of undetermined cause without inducible ventricular tachyarrhythmias and without structural heart disease.
- The member has cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm.
- The member had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angiography within the past 3 months.
- The member had an acute MI within the past 40 days.
- The member has clinical symptoms or findings that would make the member a candidate for coronary revascularization.
- The member has NYHA class IV symptoms and drug-refractory congestive heart failure and is not a candidate for cardiac transplantation or implantation of a cardiac resynchronization therapy (CRT) device that incorporates both pacing and defibrillation capabilities.
- The member has ventricular fibrillation or VT that is amenable to surgical or catheter ablation.

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## **Billing and Reimbursement**

The IHCP reimburses the cost of the implantable cardioverter defibrillator device separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

An itemized cost invoice must be submitted with the claim for the device. The invoice can be submitted by mail, either as an attachment behind the paper claim form or with a cover letter and Claim ID corresponding to an electronic claim submission, or it may be uploaded electronically along with claims submitted via the Provider Healthcare Portal. See the <u>Claim Submission and Processing</u> module and the <u>Provider Healthcare Portal</u> module for details.

# Implantable Infusion Pumps

The IHCP covers implantable devices for intra-arterial, epidural, and intrathecal infusions for the following treatments and does not require PA:

- Chemotherapy for liver cancer The implantable infusion pump is covered for intra-arterial infusion of 5-Floxuridine (FUDR) for the treatment of liver cancer for members with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver. One of the following conditions must exist:
  - The disease is unresectable.
  - The member refuses surgical excision of the tumor.
- Anti-spasmodic drugs The implantable infusion pump is covered to intrathecally administer antispasmodic drugs to treat chronic intractable spasticity in members who have proven unresponsive to less invasive medical therapy, as determined by the following criteria:
  - Documented history of at least a 6-week trial period on oral anti-spasmodics that has failed to adequately control the spasticity or has produced intolerable side effects.
  - Prior to pump implantation, the member must have responded favorably to a trial epidural or intrathecal dose of an anti-spasmodic drug.
- Opioid drugs The implantable infusion pump is covered to intrathecally administer opioid drugs to treat severe, chronic, intractable pain of nonmalignant or malignant origin in members who have proven unresponsive to less invasive medical therapy. The medical record must reflect the following criteria:
  - An appropriate ICD-10 diagnosis
  - The member and the person responsible for the member must be fully aware of the risks and benefits of the surgery, including the providers' mortality and morbidity experience
  - A documented medical history of less-invasive medical therapy that was tried and failed
- Other uses Coverage for other uses of implanted infusion pumps may be approved if the practitioner has documented in the member's medical record all of the following:
  - The drug is reasonable and necessary for the treatment of the individual member.
  - It is medically necessary that the drug be administered by an implanted infusion pump.
  - Food and Drug Administration (FDA)-approved labeling for the pump specifies:
    - > The drug being administered
    - > The purpose for which it is administered is an indicated use for the implantable infusion pump

#### **Noncovered Clinical Situations**

The IHCP does not cover implantation of an infusion pump in the following situations:

- The member has a known allergy or hypersensitivity to the drug (for example, oral Baclofen, morphine, and so on) being used.
- The member has an infection affecting the area of implantation.
- The member has insufficient body size to support the weight and bulk of the device.
- The member has other implanted programmable devices that, due to crosstalk between devices, may inadvertently change the prescribed settings.

## **Billing and Reimbursement**

The IHCP reimburses the cost of the implantable infusion pumps separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers.

# Lumbar Arthroplasty (Artificial Disc)

Effective July 19, 2018, the IHCP covers lumbar arthroplasty when the prosthetic intervertebral discs are approved by the FDA and the procedure is billed with CPT code 22857 – *Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar.* 

PA is required for lumbar arthroplasty, and the following criteria must be met:

- Chronic, unremitting, discogenic lower back pain and disability secondary to single-level
  degenerative disc disease (DDD) as medically necessary in a skeletally mature (fully formed and
  grown) individual
- Unremitting low back pain and significant functional impairment is refractory to at least six
  consecutive months of structured\*, physician-supervised, conservative medical management, which
  includes all the following components:
  - Exercise, including core stabilization exercises
  - Nonsteroidal and/or steroidal medication (unless contraindicated)
  - Physical therapy, including passive and active treatment modalities
  - Activity/lifestyle modification

\*Note: Structured medical management consists of medical care that is delivered through regularly scheduled appointments, including follow-up evaluation, with licensed healthcare professionals.

- Single-level disc degeneration has been confirmed on complex imaging studies, such as CT scan or MRI
- Implant will be inserted at a FDA-approved lumbar/sacral level specific to the implant being used
- · No anatomic deformity or malignancy at affected level
- No osteoporosis
- No previous lumbar surgery at affected level

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- No systemic infection or localized infection at site of implantation
- Members must be 60 years of age or younger

# Osteogenic Bone Growth Stimulators

The IHCP covers osteogenic bone-growth stimulators (OBGS), including implantable stimulators. Prior authorization is required.

The implantable stimulator is covered only for the following indications:

- Nonunion of long bone fractures
- As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed spinal fusion at the same site; or for those undergoing multiple level fusions (fusions involving three or more vertebrae, such as L3–L5 or L4–S1)

For requirements related to noninvasive osteogenic bone growth stimulators, see the <u>Durable and Home Medical Equipment and Supplies</u> module.

## **Billing and Reimbursement**

The IHCP reimburses the cost of the implantable osteogenic bone-growth stimulators separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

# Patient-Activated Event Recorder - Implantable Loop Recorder

The IHCP covers the patient-activated event recorder – implantable loop recorder (ILR) for use after a syncopal event. Claims should be billed with a primary diagnosis code that supports medical necessity. Neither the ILR nor the implantation procedure requires PA, but both are subject to retrospective review according to IHCP criteria.

The device may not be implanted in the same member more often than every 2 years (24 months). If a replacement ILR is needed, PA is required.

The IHCP covers implantation of ILRs for members who meet the following criteria:

- If a definitive diagnosis has not been made after meeting all the following conditions:
  - Complete history and physical examination
  - Electrocardiogram (EKG)
  - Negative or nondiagnostic 30-day presymptom memory loop patient demand recordings (may be either single or multiple event recordings, with or without 24-hour attended monitoring) or symptoms occurring less frequently than every 30 days.
  - Negative or nondiagnostic tilt table testing
  - Negative or nondiagnostic electrophysiological testing
- For members with cryptogenic stroke who have had a negative initial complete diagnostic evaluation including at least 24 hours of inpatient or outpatient cardiac rhythm monitoring for the purposes of detecting previously undocumented atrial fibrillation.
- The member must be capable of activating the hand-held telemetry unit.

#### **Noncovered Clinical Situations**

The IHCP does not cover implantation of the ILR device for the following situations:

- Members with presyncopal episodes
- Members failing to fulfill the indications for coverage in this policy
- Members for whom compliance or lifestyle make using external monitoring systems inappropriate

## **Billing and Reimbursement**

The IHCP reimburses the cost of the ILR separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers.

ECG analyses obtained during device insertion for signal quality and amplification purposes are considered part of the implant procedure and are not reimbursed separately.

Initial analysis and monitoring is included in the fee for insertion and should only be billed subsequent to the date of insertion.

Removal of an ILR on the same day as the insertion of a cardiac pacemaker is considered part of the pacemaker insertion procedure and is not reimbursed separately.

# Phrenic Nerve Stimulator (Breathing Pacemaker)

The IHCP covers the phrenic nerve stimulator (breathing pacemaker) subject to specific coverage criteria. Prior authorization is required for the phrenic nerve stimulator and its implantation.

PA requires medical documentation of at least one of the ICD diagnosis codes listed for the phrenic nerve stimulator in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers. The diagnosis code must be used when submitting requests for PA.

For some of these diagnoses, additional medical criteria apply:

- For stable, nonacute quadriplegics and other spinal-cord or brain-stem injured members (diagnosis codes G82.50, G82.51, and G82.52), all the following criteria must be met:
  - The member is oriented to name, date, and place.
  - The member's mobility will be improved. Patient will be able to be out of bed and be mobile per wheelchair, which may include employment or school attendance. Increased mobility will allow the patient to function without the interference of large equipment.
  - The member's skin integrity will be better maintained because of increased mobility.
  - The member has the capacity to be productive. He or she will more easily perform cognitive tasks within physical limitations.
  - The member will be better able to eat and swallow.
- For idiopathic sleep-related nonobstructive alveolar hypoventilation (G47.34) and congenital central alveolar hypoventilation syndrome (G47.35), the following criteria must be met:
  - Other treatments have been attempted and failed. Documentation by a specialist in otolaryngology or pulmonology of treatment attempts must accompany the PA request.
  - The requesting physician will present sleep studies demonstrating clinically significant central sleep apnea and/or hypoventilation requiring respiratory support other than oxygen supplementation for greater than or equal to 16 hours per day currently.
  - The member must have a diagnosis of central sleep apnea (CSA) and have failed to maintain an appropriate PO<sub>2</sub> level (oxygen partial pressure) with continuous positive air pressure (CPAP) and bi-level continuous positive airway pressure (BiPAP) treatments.

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Policies and procedures as of August 1, 2019 Version: 4.0 Note: The phrenic nerve stimulator should **never** be recommended for treatment of **obstructive** sleep apnea.

The primary objective of implanting the phrenic nerve stimulator is to allow the member to return from a skilled nursing facility to a home environment and be more independent. Therefore, the following criteria are mandatory for prospective candidates requesting this device:

- Functional lungs and diaphragm muscle and both phrenic nerves
- Absence of infection in orofacial, neck, chest, or abdomen and of any suspicion of systemic infection, including sepsis
- A clear and adequate upper airway (including nasopharynx, pharynx, and larynx)
- Family support that includes an unpaid, physical caregiver of adequate quality and the availability of nursing and medical care

## **Billing and Reimbursement**

Diagnosis codes to use when billing for the phrenic nerve stimulator are listed in *Surgical Services Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

The IHCP reimburses the cost of the phrenic nerve stimulator separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers.

# Spinal Cord Stimulators

The IHCP covers spinal cord stimulators (SCS) with prior authorization. PA requires medical documentation of at least one of the ICD diagnosis codes listed for the SCS in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers. The diagnosis code must be used when submitting requests for PA. Diagnoses of chronic, nonmalignant, neuropathic pain are considered for approval on a case-by-case basis by a pain management consultant, if all other PA criteria are met.

SCS treatment must be evaluated in a 3- to 7-day trial stimulation period before permanent implantation. Providers must request PA for both the trial and permanent phases of this service.

#### **Trial Stimulation Period**

The first phase of SCS must be evaluated prior to a permanent SCS implantation. Members must meet the following criteria for the 3- to 7-day trial stimulation period:

- The implantation of the stimulator is used only as a treatment of last resort for members with chronic intractable, nonmalignant pain.
- There is documented pathology, such as an objective basis for the pain complaint.
- There must be documentation of failure of at least 6 months of conservative treatment, including at least three of the following:
  - Pharmacological therapy
  - Surgical management
  - Physical therapy
  - Psychological therapy
- The member must not be a candidate for further surgical interventions.

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- An evaluation must be performed by a physician experienced in treating chronic pain, which includes
  documentation of a psychological evaluation, as well as a consultation from another pain specialist,
  that indicates the member would benefit from SCS.
  - The psychological evaluation should reveal no evidence of an inadequately controlled mental health problem (such as alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement
- The member must not have any existing, untreated drug addictions.

## Permanent SCS Implantation

Following the trial stimulation period, PA will be approved for permanent implantation after the following criteria have been met:

- All six criteria for a 3- to 7-day trial implantation period must be met.
- The trial implantation must show a 50% reduction in pain for at least 2 days in order to receive approval for permanent implantation. Providers must submit documentation of successful treatment.
- IHCP providers are directed to use the Multidimensional Affect and Pain Scale, the Brief Pain Inventory, and/or the Faces Pain Scale to measure pain levels. Providers are responsible for deciding which pain measurement scale is appropriate for each member.

## Intractable Angina

The IHCP covers SCS for the treatment of intractable angina for members whose pain is unresponsive to standard therapy. Following the trial stimulation period, PA will be approved for permanent implantation after the following criteria have been met for the treatment of intractable angina:

- Angiography documents significant coronary artery disease, and the patient is not a candidate for percutaneous transluminal coronary angiography (PTCA) or coronary artery bypass grafting (CABG).
- The angina pectoris is NYHA class III or IV.
- Reversible ischemia is documented by symptom-limited treadmill exercise tests.
- The member has had optimal pharmacotherapy for at least 1 month, including the maximum tolerated doses of at least two of the following medications have failed to adequately improve angina symptoms:
  - Long-acting nitrates
  - Beta-adrenergic blockers
  - Calcium channel blockers
- There is documentation of successful trial spinal cord stimulator implantation showing a 50% reduction in pain for at least 2 days.

## Billing and Reimbursement

Diagnosis codes to use when billing for SCS services are listed in *Surgical Services Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

The IHCP reimburses the cost of the spinal cord stimulator separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers.

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#### Stents

The IHCP limits coverage of CPT code 37215 – *Insertion of stents and blood clot protection device in neck artery, open or accessed through the skin* to specific diagnoses. The applicable ICD-10 diagnosis codes are listed in *Surgical Services Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

The IHCP covers CPT code 61635 – *Transcatheter placement of intravascular stent(s), intracranial (eg, artherosclerotic stenosis), including balloon angioplasty, if performed.* Prior authorization is required and is limited to members with stenosis at or above 70% for whom all other additional medical treatments have failed.

Separate reimbursement is not available for stents, as they are considered bundled into the reimbursement for the surgery.

For intraocular stent coverage and billing information, see the *Vision Services* module.

# Transcatheter Aortic Valve Replacement/Implantation

The IHCP covers transcatheter aortic valve replacement/transcatheter aortic valve implantation (TAVR/TAVI). No PA is required.

Separate reimbursement is not available for the transcatheter aortic valve itself, as it is considered bundled into the reimbursement for the surgery.

# Vagus Nerve Stimulator

The IHCP covers the vagus nerve stimulator (VNS) and the implantation, revision, programming, and reprogramming for members of all ages with medically intractable partial onset seizures who are not otherwise surgical candidates. Prior authorization with documentation of medical necessity is required.

The physician must obtain PA for the implantation procedures, regardless of inpatient or outpatient setting. The following documentation must be maintained in the medical record and submitted with the PA request:

- Documentation that an evaluation has been made by a neurologist
- Documentation of the member's type of epilepsy
- Documentation that the member's seizures are medically intractable (member continues with an unacceptable number of seizures with adequate treatment with two or more anti-epileptic drugs for a period of at least 12 months)
- Documentation that the member is not an intracranial surgical candidate or that surgery has been unsuccessful (for example, the member is not a surgical candidate due to multiple epileptic foci)

In situations where complicating factors require the procedure to be performed on an inpatient basis, medical history and records must support the need for the hospital admission. When the procedure is performed in an inpatient setting, PA is required for the admission but not for the VNS; reimbursement for the VNS is included in the DRG for the inpatient procedure.

#### **Noncovered Clinical Situations**

The IHCP does not cover vagus nerve stimulators for resistant depression or treatment of chronic pain.

## **Billing and Reimbursement**

Diagnosis codes to use when billing for the VNS are listed in *Surgical Services Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

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The IHCP reimburses the cost of the VNS separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. Providers must bill the device on a professional claim (*CMS-1500* claim form or electronic equivalent). See the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers.

Note: In situations where a complicating factor is present and the member requires admission to the hospital for the procedure, the procedure and device are reimbursed according to the appropriate DRG payment. The hospital stay must be billed as an institutional claim and must include a secondary diagnosis indicating a complicating factor that necessitated inpatient admission. DRG payments for inpatient procedures with complicating factors include reimbursement for the device. Hospitals cannot receive additional reimbursement, outside the DRG payment, for the cost of the device when the service is performed on an inpatient basis.

The IHCP created two HCPCS codes by appending the U1 modifier for providers to use when billing neurostimulator device components **for VNS diagnoses only**:

- L8680 U1 Implantable neurostimulator electrode, each, VNS only
- L8686 U1 Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension, VNS only

Claims submitted for HCPCS codes L8680 U1 and L8686 U1 with diagnosis codes not listed in the *ICD Diagnosis Codes for VNS Services* table will be denied with explanation of benefits (EOB) 4037 – *This procedure is not consistent with the diagnosis billed. Please verify and resubmit.* 

HCPCS codes L8680 U1 and L8686 U1 are manually priced. Consistent with the IHCP's manual pricing methodology for DME, these codes are reimbursed at 75% of the manufacturer's suggested retail price (MSRP). Providers are required to submit **both** proof of the MSRP **and** an itemized cost invoice with the claim. (See the <u>Durable and Home Medical Equipment and Supplies</u> module for more information about MSRP documentation and cost invoices.)

Note that, when billing neurostimulator device components for **non-VNS use**, providers should continue to bill HCPCS codes L8680 and L8686 *without* the U1 modifier. These codes pay at a flat fee, as indicated on both the Outpatient and Professional Fee Schedules, accessible from the <u>IHCP Fee Schedules</u> page at in.gov/medicaid/providers.

## Ventricular Assist Devices

The IHCP covers ventricular assist devices (VADs) – including those designed for use in the left ventricle (LVADs), the right ventricle (RVADs), or both ventricles (BiVADs) – in the circumstances listed in Table 10, when the indicated medical criteria are met.

Table 10 - Medical Criteria for VAD

Circumstance	Medical Criteria
Postcardiotomy Cardiogenic Shock	The member's ventricular dysfunction continues after maximum medical therapy
	or
	As a means of myocardial recovery support for members who are unable to be weaned off cardiopulmonary bypass with maximal inotropic support and use of an intra-aortic balloon pump (IABP)

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The member is listed as a candidate for heart transplantation by a Medicare- and Medicaid-approved heart transplant center.  — If the VAD is implanted at a different site than the Medicare- and
Medicaid-approved transplant center, the implanting site must receive written permission from the Medicare- and Medicaid-approved center under which the patient is listed for transport prior to implantation of the VAD.
The member must not be a candidate for heart transplant.  The member must have chronic end-stage heart failure (NYHA class IV) for at least 90 days, and have a life expectancy of less than 2 years.  The member's class IV heart failure symptoms must have failed to respond to optimal medical therapy for at least 60 of the last 90 days.  Medical therapy must include the following treatments:  Salt restriction  Diuretics  Digitalis  Beta-blockers  Angiotensin receptor blockers (ARBs) or angiotensin-converting enzyme (ACE) inhibitors (if tolerated)  Left ventricular ejection fraction (LVEF) must be less than 25%.  The member has demonstrated functional limitation with a peak oxygen consumption of less than 12ml/kg/min or continued need for IV inotropic therapy due to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion.  The member has the appropriate body size (greater than or equal to 1.5m²) to support the LVAD implantation.  VAD implantation must occur at a Medicare- and Medicaid-approved heart transplant center.

A VAD is covered for postcardiotomy cardiogenic shock or bridge-to-transplant only if it has received approval from the FDA for the intended purpose, and only if it is used according to the FDA-approved labeling instructions for that intended purpose. A VAD is covered for destination therapy only if it has received approval from the FDA for destination therapy or as a bridge-to-transplant, or has been implanted as part of an FDA investigational device exemption trial for one of these two indications. Use of a non-FDA approved VAD is considered investigational and is noncovered.

Prior authorization is not required for VADs or their surgical implantation. However, members who receive bridge-to-transplant or destination therapy, and who can continue therapy on an outpatient basis, require accessory equipment and supplies for use with the VAD. Prior authorization is required for accessory equipment, patient supplies, and replacement equipment.

#### Billing and Reimbursement

Claims for implantation of VADs are subject to postpayment review. Providers must maintain documentation in the member's medical record that indicates that **all criteria** have been met for implantation of a VAD. If all the criteria for implantation are not satisfied, reimbursement of funds may be recouped, including surgical fees, professional fees, and equipment costs.

VAD implantation is performed on an inpatient-only basis; therefore, separate reimbursement for the implantable device does not apply. Reimbursement for the VAD is included within the inpatient DRG.

The hospital or DME provider purchases the power base and is reimbursed a rental payment while the equipment is used on an outpatient basis by the member. The physician must submit a PA request for the VAD power base and display module using HCPCS code L9900 – *Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS L code* and modifier RR – *Rental use.* A description of the power unit and display module should be entered with HCPCS code L9900, on a detail line of the *CMS-1500* claim form or as a claim note in the electronic professional claim. The total rental price may not exceed the purchase price. An invoice for each detail must accompany the claim when submitted.

When billing for patient supplies or replacement equipment, an invoice for each detail must accompany the claim.

# Separately Reimbursable DME When Implanted in an Outpatient Setting

Table 11 provides a quick reference for which implantable DME are reimbursable separately from the implantation procedure when the implantation is performed in an outpatient surgical setting. For specific HCPCS codes, see the *Implantable DME Separately Reimbursable in the Outpatient Setting* table in *Surgical Services Codes*, accessible from the <u>Code Sets</u> page at in.gov/medicaid/providers.

The facility provider should submit claims for these items, and only these items, on the professional claim (*CMS-1500* claim form or electronic equivalent). The IHCP permits only these items to have separate reimbursement.

Table 11 – Reimbursement for Devices When Implanted in an Outpatient Setting

Device	Separately Reimbursed?
Cardiac pacemakers	Yes
Cochlear implants	Yes
Implantable cardioverter defibrillator	Yes
Implantable infusion pump	Yes
Osteogenic bone growth stimulator (implantable)	Yes
Patient-activated event recorder – implantable loop recorder	Yes
Phrenic nerve stimulator	Yes
Spinal cord stimulator	Yes
Stent	No
Transcatheter aortic valve replacement/implantation	No
Vagus nerve stimulator	Yes

# **Noncovered Services**

For a list of noncovered surgical services, see 405 IAC 5-29 and the IHCP Fee Schedules, accessible from the <u>IHCP Fee Schedules</u> page at in.gov/medicaid/providers.

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